



Building a Better Health Service

CARE COMPASSION TRUST LEARNING

Final Report

Rapid Appraisal of the Healthcare Audit Function, Quality Assurance and Verification Division.

Final Report Date: 5th of December 2017.

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Table of Contents	Page
Introduction	3
What the HSE says about the HCA function	3
A brief history of the HCA function	3
About this rapid appraisal	4
Method	5
Findings	6
Where the HCA Function is at the moment	6
Where the HCA Function needs to be in the future	9
▪ The process for prioritising audits needs to become risk driven	9
▪ Need to increase the organisation-wide coverage and number of audits	9
▪ Tracking and driving recommendations implementation and links to QI needs to be strengthened	10
▪ Training and support to build capability for local HCA enabling more sophisticated local and national HCA	10
▪ Healthcare Audit needs enhanced visibility and profile	11
▪ The need to develop processes for gaining understanding of reasons for non-compliance	11
▪ Need for enhanced audit methods to enhance data integrity / usefulness	12
▪ Need for enhanced exploitation of ICT	13
▪ Need to develop capacity for rapid audit response to emerging concerns	13
▪ Need to link HCA work with patient/service user experience and safety improvement	14
How to get from where we are to where we need to be	15
▪ A model for continuous sustainable improvement in outcomes	15
→ Safety intelligence	15
→ Evidence informed standards	16
→ A focus on outcomes/goals	16
→ Audit is not the only method of monitoring performance	16
→ Improvement occurs in a complex environment	17
▪ Recommendations for the future	18
The Wider Audit Context	19
The HCA Function and the HSE Assurance Framework	19
Level I Assurance	20
Level II Assurance	20
Level III Assurance	20
▪ Healthcare Audit	20

▪ Internal Audit	20
Level IV Assurance	21
Other agencies that support/conduct audit in the HSE	21
The National Clinical Excellence Committee (NCEC)	21
National Office for Clinical Audit (NOCA)	22
RCPI Specialist Quality Improvement (SQI) Programmes	22
Other agencies that support/conduct audit in the HSE	22
Independence and impartiality	22
Integrity of data for quality assurance and improvement purposes	23
National Audit in NHS Scotland	24
National Audit in NHS England	25
Appendix 1: Table showing details of key agencies that conduct audit within the HSE with list of external agencies that may undertake audit within the HSE	26
Appendix 2: Recommendations with expanded details	29

Introduction

What the HSE says about the HCA function:

The HSE Website refers to both the *quality assurance* role and the *quality improvement* role of the Healthcare Audit (HCA) function stating that the HCA Function provides *assurance* to the HSE that the services the HSE provides meet statutory obligations and are delivered in accordance with best practice. It goes on to state that the HCA function plays a key role in the HSE's overall assurance framework and that it supports the HSE in achieving its objectives by:

- Providing valuable and reliable information to inform decision making
- Identifying good practice for sharing, learning and implementing across the system
- Testing the effectiveness of internal controls that are identified to manage risk, and
- Providing evidence for managers in relation to signing the statement of internal control.

It then states that HCA is a *quality improvement* activity conducted by auditors using agreed procedures.

Summary National Healthcare Audit reports are published to the HSE website. Published reports to date - and the audits within the 2017 operational plan - include both clinical and non-clinical audits that span every service delivery division of the HSE, and that relate to key safety issues such as the communication of patient critical information; and the detection and response to rapid deterioration in patients.

A brief history of the HCA Team

The HCA Team was established in 2010. At that time the number of members on the Team was 19 and the number of national audits per annum was in the vicinity of 18 (including an average of 6 individual sites audits per each individual national audit, totalling approximately 108 individual site audits per year).

Due to changes in structures in early 2015, the HCA function was reduced by almost 40%. This reduction significantly impacted on the ability of the Team to conduct National Healthcare Audits at the rate they had formerly achieved.

In 2016 and 2017 some investment was made in the function. As a result HCA staffing levels increased to 11 in 2016 and should be 19 by the end of 2017 bringing the number back to 2014 levels.

About this rapid appraisal

A new Assistant National Director for Healthcare Audit (HCA) was appointed on the 10th of April 2017 to replace the outgoing post-holder who retired in November 2016.

The new post holder undertook a rapid appraisal of the Healthcare Audit function whereby she engaged with key stakeholders to determine stake-holders views on the following:

- a) What stakeholders think of where the HCA function is at the moment in terms of using its resources to make the greatest possible safety impact?
- b) In an ideal world, where do stakeholders think HCA needs to be in the future in terms of using its resources to make the greatest possible safety impact?
- c) How do stakeholders think the HCA function can get from where it is to where it needs to be, and what specific steps and actions the HCA function needs to take to get there?

The objective of this Rapid Appraisal was to learn the views of key stakeholders in relation to the above to inform the approach and methods of the Healthcare Audit Team and how Healthcare Audits are prioritised and scheduled from January 2018 and into the future.

Method

Between April and July 2017, 46 key stakeholders were interviewed. Interviewees included patient/service user representatives, practicing clinicians, and representatives from the following:

- Service User Representatives
- HSE Risk Committee
- Hospital Group CEO's and Clinical Directors
- Community Health Organisations Chief Officers
- National Patient Safety Office (NPSO) within the Department of Health (DoH)
- HSE Leadership Team/National Directors
- Healthcare Audit Team Members
- Quality Assurance and Verification Division (QAVD) Management Team
- Quality Improvement Division (QID)
- Acute Hospital Division
- Social Care Division
- Primary Care Division
- Health and Well-being Division
- Mental Health Division
- National Ambulance Service
- Internal Audit Division

Please see figure 1 below for further details showing the breakdown of interviewees.

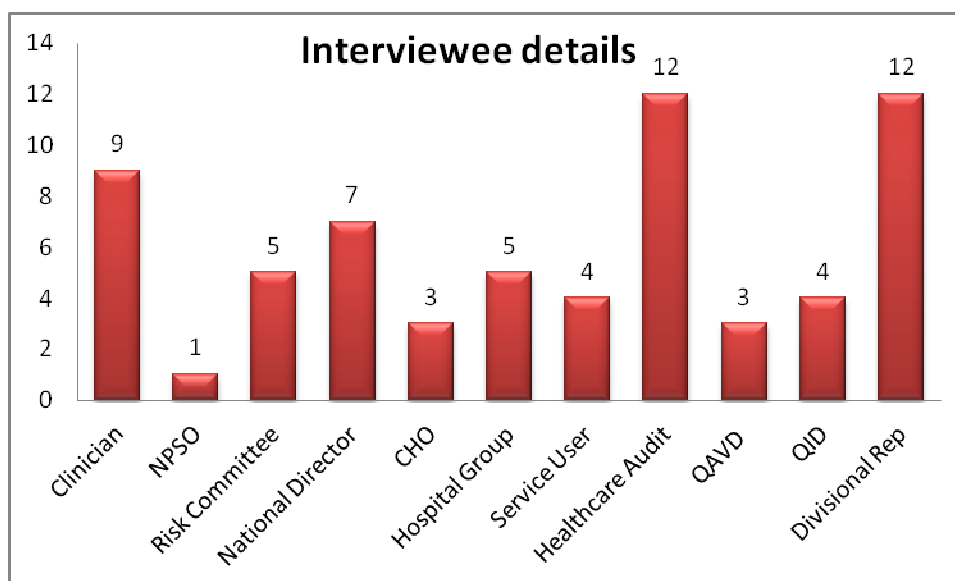


Figure 1: Showing breakdown of interviewees. (**Note:** Some interviewees fell into more than one category. This explains the discrepancy between the total figure of 65 as per this table compared with the total figure of 46 interviewed).

Interviewees were invited to attend a face-to-face meeting or a teleconference with the AND for HCA based on which was most convenient for the interviewee. Interview durations ranged from between approximately 20 minutes to over an hour. Interviews focused on the following three questions.

- a) What the interviewee thought of where the HCA function is at the moment in terms of using its resources to make the greatest possible safety impact?
- b) In an ideal world, where the interviewee thought the HCA function needs to be in the future in terms of using its resources to make the greatest possible safety impact?
- c) How the interviewee thought the HCA function could get from where it is to where it needs to be, and what specific steps and actions the HCA function needed to take to get there?

Responses were thematically analysed to inform a draft report. The draft report and a document containing anonymised raw responses were circulated to all 46 interviewees to give them an opportunity to review the drafts and to give feedback either confirming that they were satisfied that their views were satisfactorily reflected in the drafts, or to give feedback to enhance how their views could be better reflected in the final report. These drafts were also circulated to additional stakeholders within HSE Internal Audit, QAV National Incident Management and Learning Team (NIMLT), and the National Patient Safety Office (NPSO) in the Department of Health (DoH).

Of the 46 interviewees, 38 (i.e. 82.61%) gave feedback to the draft report. Of the interviewees that gave feedback, 11 (i.e. 28.95%) confirmed that their views were satisfactorily reflected within the drafts and that they had no further feedback. The remaining 27 (i.e. 71.05%) respondents gave additional feedback which informed this final report.

Findings

Where the HCA Function is at the moment

One interviewee put the role of Healthcare Audit eloquently as follows:

“The strength of any organisation can be gauged by the strength of their internal self awareness and HCA is an important part of this....”

One National Director stated the following about National Healthcare Audits related to their Division:

“I found that Healthcare Audits were excellent.... The audit outcomes were not good, but the audits were very well done. The Healthcare Audit reports gave us a good platform from which to try to improve...”

A Clinical Lead stated the following about a National Healthcare Audit related to their area of work:

“It’s all about learning. National Audits provide a national perspective for learning...”

Key stakeholders frequently expressed an awareness of the value of the HCA Function in terms of quality improvement and in terms of providing assurance to the HSE for the areas that could be audited within the resources available to the Function. They often responded that, what the Healthcare Audit Function did, it did very well. But interviewees also often expressed confusion about the role of the HCA function, particularly in relation to quality improvement and/or quality assurance. They also often stated that the reach and potential impact of the HCA function was affected by its limited resources, and that the profile and visibility of the HCA function within the organisation was not as high as it should be.

Interviewees stated that the audit environment within the HSE appeared to be *“splintered”... “fragmented”... “disjointed....”* and that:

“There is a need to clarify the roles and responsibilities of the various audit structures...”

Interviewees stated the above with reference to the fact that there were various agencies that may conduct or support audit within the HSE including but not limited to the Quality Improvement Division, the HCA function, the National Office for Clinical Audit (NOCA), the Specialist Quality Improvement (SQI) programmes within the Royal College of Surgeons of Ireland (RCSI), the Clinical Programmes, the Internal Audit Function, and external regulators. This is not to say that there is not a need for these various audit functions; nor to say that they

do not individually do much work to clarify their respective roles and responsibilities. Rather, there was consensus that it would be helpful for all agencies to collaborate in relation to communicating their roles and responsibilities, and particularly, that it would be helpful for them to collaborate to ensure that there is no unnecessary overlap or omissions in important audit work. Please see Appendix 1 for further details of the various audit agencies that may conduct or support audit within the HSE - and their respective roles and responsibilities.

Where the HCA Function needs to be in the future

The process for prioritising and scheduling audits needs to become risk driven:

Interviewees identified that the process for prioritising and scheduling audits needs to be strengthened. They stated that this process needs to:

“Focus on key safety issues”.

They proposed that it should not be based on requests for audits, and that it should rather be based on information about the greatest risks to the organisation and service users; information from analysis of themes of causal factors from complaint and incident investigations; information about gaps in the controls assurance process; and concerns of service users, staff, management and the public. They stated that some resource should be allocated to respond to audit requests, particularly for quality improvement purposes - but that these should only be done if resources were available after audits related to key safety issues were conducted.

Need to increase organisation-wide coverage and the number of audits

Interviewees wished for a strong emphasis to be placed on the importance that all National Healthcare Audits - as far as it is possible and relevant - should include a mixture of both acute and community sites thus improving the organisational coverage of Healthcare Audits and ensuring that community services are as well represented within Healthcare Audits as Acute Services. It was identified that this would enhance visibility of care pathways across services related to audit topics and themes including enhanced visibility of the interfaces between services for assurance and quality improvement purposes. It is noteworthy that issues at such interfaces are often associated with poor organisational quality, safety and performance.

Currently, approximately 15 National Healthcare Audits are completed per annum, with each National Audit comprising approximately 6 individual site audits. It was proposed to increase the number of National Healthcare Audits and the number of individual site audits that fall under each National Audit to enhance data validity, reliability and generalisability; to enhance the assurance that can be provided to the organisation; and to enhance the availability of high quality data for quality improvement purposes.

Tracking recommendation implementation and links to QI need to be strengthened:

One interviewee stated that:

“Healthcare Audit recommendations needed to be taken as seriously as Internal Audit recommendations..... there needs to be sanctions for non-implementation of recommendations”.

It was proposed that there was a need for a robust process for monitoring and identifying verifiable evidence of implementation of recommendations and quality and safety improvements in response to Healthcare Audit reports including verifiable evidence that implementation has culminated in risks being eliminated or reduced as far as is reasonably practicable, and if not, verifiable evidence that risks have been reassessed and appropriately managed. This would include a programme of re-audits with a cut-off point for no further re-audits related to satisfactory compliance and safety improvement.

Interviewees pointed to the KPI's that are in place for implementation of recommendations arising from Internal Audit whereby 75% of recommendations that are risk rated as high or medium - must be implemented within 6 months and 95% of such recommendations must be implemented within 12 months, and that this is accounted for through the National Performance and Oversight Process. They suggested that a similar approach should be implemented for Healthcare Audit including the escalation of incidents of failure to implement recommendations in line with this KPI - to the Risk Committee.

Interviewees also identified that it was very important to strengthen HCA processes for demonstrating the link between HCA findings and quality improvement that is meaningful to patients and service users, and to continue to translate good audit outcomes into opportunities for sharing learning and generating improvement throughout the organisation.

Training and support to build capability for local Healthcare Audit enabling more sophisticated local and National Healthcare Audits:

Hospital Group CEO's and Chief Officers emphasised that they needed support to build their local quality improvement and quality assurance capability and capacity and that they required support from National Functions, including the Healthcare Audit Function, in achieving this.

It was proposed that this would include co-ordinating the following with other Quality Improvement functions that exist:

- a) building on the work of the Quality Improvement Division related to Clinical Audit training and support
- b) leveraging the professional regulatory requirement for healthcare professionals to conduct clinical audits in a manner that also addresses the strategic Healthcare Audit needs of the organisation
- c) developing policies, procedures, protocols and guidelines to support local Healthcare Audit Delivery, and co-ordination of training and support to implement these.

It was identified that this would mean that the Healthcare Audit Function could build on local Healthcare Audit work including:

- Assisting the HSE to identify variation in compliance across the healthcare system
- Testing/verifying local audit findings
- Creating a whole organisation wide picture of healthcare audit findings related to compliance with best practice and outcomes across services, and patient pathways.

It was further identified that this would improve the sophistication of the assurance that could be given to the HSE, and the usability of audit data for both informing and measuring quality and safety improvement.

Healthcare Audit needs enhanced visibility and profile:

Interviewees identified that the Healthcare Audit Team does excellent and important work, but that it does not have a high enough profile within the organisation. They proposed that the HCA consider using the following methods of enhancing the HCA functions visibility and profile:

- Publication of site reports in addition to Summary National Healthcare Audit reports
- Promoting the work of the HCA Team via HSENet
- The use of E-zines
- Attendance at and presentations at meetings/conferences etc.

Need to develop processes for gaining understanding of reasons for non-compliance:

Some stakeholders stated that – while Healthcare Audit does good work on auditing compliance against standards - it should consider expanding its scope to include processes for gaining an understanding of the reasons for non-compliance so that recommendations address the reasons for non-compliance. They identified that there were risks in this and that processes should be piloted first to ensure they achieve the objective of enabling Healthcare

Audit to generate recommendations that are more closely linked to the reasons for non-compliance and therefore more likely to have a greater positive impact on improvement.

Contrary to this, some interviewees were clear that processes for understanding the reasons for non-compliance were outside the scope of audit, and that if an audit function were to become involved in such processes - they would cease to be independent of operations in the manner that audit functions should be independent in order to ensure the integrity of audit processes and data. Interviewees with these opposing ideas did agree on the following in relation to this matter:

1. Someone should be responsible for processes for gaining understanding of non-compliance whether or not it is the Healthcare Audit function.
2. Audit is valuable in making managers of services aware of non-compliance. Managers are then responsible for identifying the reasons for non-compliance. Re-audit is then an opportunity to determine whether the solutions managers implemented to address non-compliance contributed to improved compliance.
3. It is acknowledged that the reasons for non-compliance (i.e. the gap between work-as-imagined by the standard makers and work-as-done by those at the frontline) are often complex and related to sophisticated systems and human factors issues. Non-compliance may represent workarounds that frontline workers adopt to facilitate performance in sub-optimal conditions, (including workarounds to overcome poor quality standards) which in some situations may be the reason the system can perform, and in other situations may lead to catastrophic system failures. Managers may need support in identifying the causes of non-compliance in these complex situations and Healthcare Audit should generate data that contributes to understanding this including highlighting weaknesses in standards. Furthermore, it is acknowledged that the current practice whereby the Healthcare Audit function identifies variations in compliance, and also identifies opportunities for learning from sites that are complying well - is an important trigger for linking the sites with poor compliance with sites that comply well for sharing learning purposes.

Need for enhanced audit methods to enhance audit data integrity and usefulness:

Interviewees stated that, even though audit sample size may be small, the current quality of audits is excellent and audit reports provide important information for learning and quality improvement. At the same time, interviewees referred to the need to continuously enhance

audit methods including methods of sampling, statistical analysis methods, processes for eliciting, accepting and rejecting feedback from stakeholders to in-turn continuously improve the validity, reliability¹ and generalisability of audit data for assurance and quality improvement purposes.

A strong theme in interviewee responses related to the importance of ensuring that the standards the HCA function were measuring compliance against, were evidence based. Specifically, interviewees referred to the need for ensuring that standards that the HCA function was measuring compliance against, and which were developed post December 2016, should be checked to ensure that they were developed in line with the HSE's December 2016 Framework on the development of Policies, Procedures, Protocols and Guidelines. Interviewees were clear that time and energy spent auditing compliance against standards that were not evidence based, was a waste of audit time and energy.

Need for enhanced exploitation of ICT:

It was proposed that the Healthcare Audit Function should build its ICT and analytical capacity and capability including:

- enabling access to data available on existing ICT platforms
- developing new ICT solutions - for data collection and analysis purposes
- improving sampling methods (including sample size and representativeness) and statistical analysis capability

It was identified that all of the above would enhance data integrity which would in turn enhance the assurance that can be given to the HSE, and the usability of the data for both informing and measuring quality and safety improvement.

Need to develop capacity for rapid audit response to emerging safety concerns:

It was proposed that the Healthcare Audit Team should develop a special investigation function along the lines of the equivalent function within the Internal Audit Function – which has the capacity and capability to conduct additional unscheduled National Healthcare Audits in response to emerging issues identified by the various streams of safety intelligence such as through data from risk registers, complaint and incident investigations, the controls assurance process, and concerns raised by management, staff, and the public.

¹ Reliability is a concept related to data quality that has to do with whether repeated efforts to measure the same phenomenon come up with the same answer.

Need to link HCA work with patient/service user experience and safety improvement.

Last, but not least, there was consensus that service user representative(s) should be involved in the prioritising, scheduling, design and conduct of Healthcare Audits, and that audits should consider the service users experience. There was equal consensus that there should be a very strong focus on identifying positive outcomes for service users and staff in response to Healthcare Audit reports.

How to get from where we are to where we need to be

Finally, interviewees were asked their views about what actions or steps the Healthcare Audit Function needed to take to move from where it currently is to where it needs to be to achieve the greatest possible safety impact with the resources it has available to it.

A model for continuous sustainable improvement in outcomes.

Figure 2 below shows a model of how interviewees perceived the various factors that inform sustainable improvement in outcomes, and the position and role of the Healthcare Audit Function within this model.

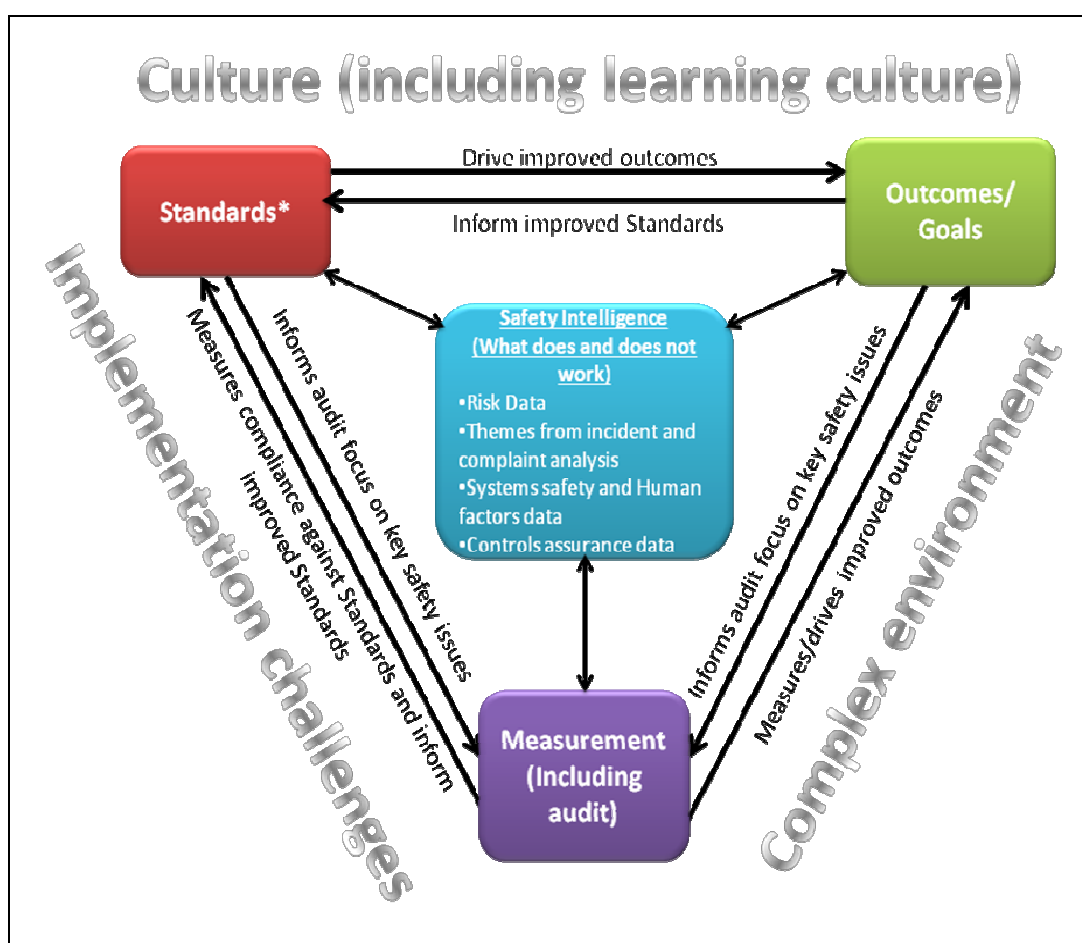


Figure 2: Showing a model of how interviewees perceived the various factors that influence outcomes and the position and role of healthcare audit within this model.

*: Denotes that standards includes Policies, procedures, protocols and guidelines (PPPG's)

Safety Intelligence

Interviewees identified that Safety Intelligence should comprise of risk data, themes from the analysis of complaint and incident investigations, systems safety and human factors data, controls assurance data and data from research. They identified that this information needed

to be triangulated to give an overall view of safety. They emphasised that the quality of the overall safety intelligence was a function of the quality of the data from the individual data sources and as each data element improves, such as the quality of data from audits and data from serious incident investigations – the quality of the overall safety intelligence would improve.

Evidence informed Standards

Interviewees identified that compliance with evidence informed standards (including policies, procedures, protocols and guidelines (PPPG's)) was a cornerstone of ensuring continuous sustainable improvement in outcomes for patients and service users and that audit should drive improving compliance with such PPPG's and consequently it would drive improved outcomes. They emphasised that the sources of evidence that should inform policies included learning from risk, incident, and complaint analysis, learning from audit, and learning from research. They conveyed concern that compliance with PPPG's that were sub-optimal would not result in sustainable improvements in patient outcomes, and that time and energy trying to drive compliance with such PPPG's, including auditing compliance against them - would be a waste of resources. Finally, they suggested that ensuring that PPPG's that were developed since the publication of the HSE Framework for Developing PPPG's (December 2016) were developed in compliance with this Framework should be considered as part of the Healthcare Audit process as a means of ensuring that PPPG's are always as evidence based and as effective as they can possibly be.

A focus on outcomes and goals

Interviewees responded that it was most important for HCA work to keep a focus on outcomes and goals and that HCA should focus on issues that are most likely to contribute to improved patient outcomes and to enable the organisation to achieve its goal of:

“A healthier Ireland with a high quality health service valued by all.”

Interviewees referred to the importance of learning from both good outcomes and bad outcomes i.e., not just learning about why things go badly, but also learning about why things go well. They highlighted that the practice whereby HCA reports identify good practice for sharing, learning and implementation across the system - is important in this regard.

Audit is not the only method of measuring performance, but it is an important one

Interviewees identified that, while audit is not the only method of measuring system performance, it is an important one. It is for this reason, that it is so important to consider the wider audit context, including how audit data feeds into the organisations safety intelligence, and including how it contributes to quality assurance and quality improvement.

Improvement occurs within a complex environment

Interviewees identified that improvement occurs within a complex environment where sustainable improvement in outcomes is a function of optimal structures and processes on the one hand, but also optimal culture and relationships on the other hand. It was recognised that audit of compliance against standards focuses on the technical aspect of the health service environment, and that while this is an important part of achieving sustainable improvement in outcomes, it is not the complete solution. The need to develop capability and capacity within the HSE to address some of the social aspects of the problem such as by exploring how to incorporate Systems Safety and Human Factors science into understanding causes of non-compliance - was identified. Using implementation science to implement effective solutions to address non-compliance was also identified as important.

As stated previously, interviewees did recognise that this work could be outside of the scope of the role of any audit function, and indeed, that if the HCA function were to get involved in this work they would be getting involved in operations to the extent that it would no longer be possible to be considered an independent audit function.

It was recognised that the Quality Improvement Division (QID) and Services are considering these matters and that this work is very important if the potential impact of Healthcare Audit on safety improvement is to be fully realised.

Recommendations for the way forward

Below is a summary of the actions interviewees believed needed to be taken to bring the HCA function from where it is to where it needs to be to deliver even higher quality audit data to achieve optimum assurance and continuous sustainable improvement in patient outcomes (See appendix 2 for greater detail related to these recommended actions):

Recommended actions for the future.	
1	Actively engage service users/patients in prioritising, scheduling, designing and conducting Healthcare Audits.
2	Develop and implement a process of prioritising and scheduling Healthcare Audits based on the greatest risks to service users and the organisation.
3	To continue to improve HCA methods and data integrity and usefulness, including enhancing capability and capacity for sampling, use and development of ICT tools and platforms, and statistical analysis.
4	Increase the number and organisation-wide coverage of Healthcare Audits.
5	Develop capacity for rapid audit response to emerging safety concerns.
6	Develop and implement a process for tracking and driving implementation of audit recommendations and linking audits to specific quality improvements and outcomes.
7	Deliver training and support to build the capacity for local Healthcare Audit enabling more sophisticated national Healthcare Audit including testing and validation of local audit findings by HCA.
8	Enhance the profile of the HCA function within the HSE through publication of reports, the use of the internet and E-zines, and attending and presenting at conferences.
9	<p>To have a national strategic approach to audit that would address the problem of fragmentation, omissions and overlaps in audit work. It is recognised that there are many stakeholders in this in addition to the Healthcare Audit function and that much of this is outside the control of the Healthcare Audit function. For their part, in the interim, it is recommended that the HCA function develop their own strategy that should eventually be aligned with any National Audit Strategy that may be developed.</p> <p>Healthcare Audit Strategy</p> <p>Develop and implement a 3 year Healthcare Audit Strategy</p> <p>National Audit Strategy</p> <p>Develop and implement a national audit strategy and framework for the HSE which includes a cohesive National Audit Plan requiring clarifying the roles of the various audit agencies to prevent overlaps and omissions in audit work. This strategy should include mechanisms for evaluating the quality of audits that consider the validity, reliability and generalisability of audit data; and the National Clinical Excellence Committee tools for quality assuring audits.</p>

The Wider Audit Context

The HSE Risk Committee requested that this report would consider the wider audit and assurance environment related to the HSE, and National audit within the NHS. The following two sections of this report address these topics. It should be stated at the outset that no function equivalent to the HSE HCA function was identified within the NHS or other Health System in a developed country. That is to say, no function that was located within the health system but was independent of the health service delivery system and which audited compliance against legislation and standards related to both clinical and non-clinical issues within both acute and non-acute services - was identified.

The HCA Function and the HSE Assurance Framework.

From the stakeholder interviews, it was identified that the levels of assurance were not clearly defined and/or understood by all stakeholders. The HSE Code of Governance (October 2015) states that the HSE Assurance Framework is composed of four levels as shown in figure 3 below.

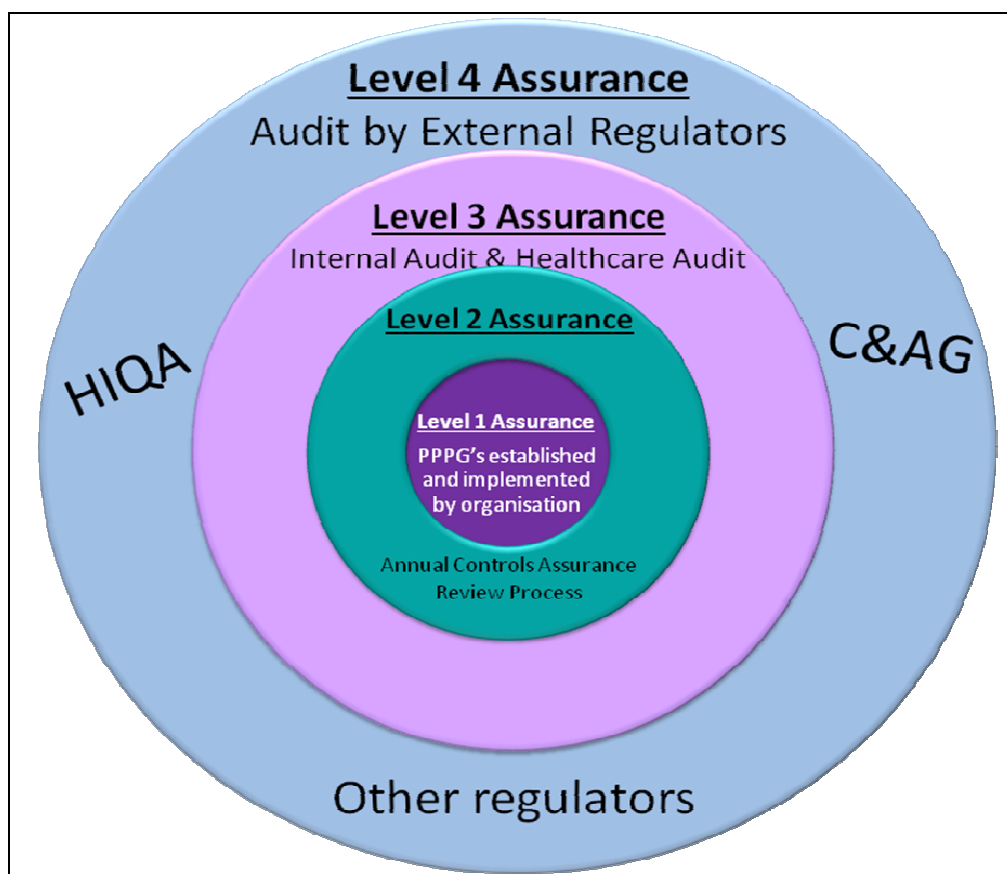


Figure 3: Showing the four levels of assurance according to the HSE Assurance Framework (Source HSE Code of Governance (October 2015)).

Level I Assurance – Procedures and Polices Established and Implemented by the Organisation.

Level II Assurance – Line and Operational Management Oversight and Review of Adherence to Organisational Procedures. Managers are responsible for carrying out checks of compliance with Policies, Procedures, Protocols and Guidelines (PPPG's) to satisfy themselves of compliance and to take necessary corrective action to address any deficiencies identified. The completion of the Annual Controls Assurance Review Process by managers forms part of Level II Control and assurance.

Level III Assurance – Internal Audit and Healthcare Audit.

Internal Audit and Healthcare Audit review systems, processes and controls on a sample basis. Investigations and reviews are also undertaken by Internal Audit. All findings and recommendations identified by Internal Audit are reported to management and the Audit Committee. All findings and recommendations identified by Healthcare Audit are reported to management and to the National Director for Quality Assurance and Verification. Management is responsible for implementing Internal Audit and Healthcare Audit recommendations in a timely manner.

- **The Healthcare Audit function** conducts a comprehensive programme of audits of compliance with both clinical and non-clinical standards in all services throughout the HSE including acute and community services. The purpose of this work is to provide assurance that controls and procedures are operated in accordance with best practice and for quality improvement purposes. The scope of Healthcare Audit covers all systems and activities throughout the HSE and bodies totally or partially funded by the HSE. The Assistant National Director (AND) for HCA reports to the National Director for the Quality Assurance and Verification Division (QAVD) who reports to the Director General (DG) with a dotted line reporting relationship to the Risk Committee, making HCA independent of HSE operations and service delivery functions.
- **The Internal Audit Division** is responsible for ensuring that a comprehensive programme of internal audit work is carried out throughout the HSE (including financial audit, and ICT audit). The purpose of this work is to provide assurance that controls and procedures are operated in accordance with best practice and with the appropriate regulations, and to make recommendations for improvement of such controls and procedures. The scope of Internal Audit covers all systems and activities throughout the HSE and bodies totally or partially funded by the HSE. The National

Director for Internal Audit reports to the Chair of the Audit Committee with a dotted line relationship to the DG for “*pay and rations*” making Internal Audit independent of HSE operations and service delivery functions.

Level IV Assurance – External Audit.

External Audit can relate or Financial of Healthcare Audit. The C&AG, which is the External Auditor for the HSE, carries out an annual audit of the Annual Financial Statements and reports its findings to the Public Accounts Committee.

External Regulatory bodies also carry out audits and reviews within the healthcare arena.

Examples of such bodies include the Health Information and Quality Authority (HIQA), Mental Health Commission (MHC), Irish Pharmaceutical Society (IPS), Health Products Regulatory Body etc.

Please see appendix 1 for further details of agencies that support and/or conduct audit within the HSE.

Other agencies that support/conduct audit within the HSE²

- **The National Clinical Excellence Committee (NCEC).** The NCEC is a Ministerial committee of health system stakeholders, which is supported by the Department of Health’s National Patient Safety Office. The NCEC role is to provide strategic leadership for the national clinical effectiveness agenda, which includes guidelines, audit and practice guidance. The role includes prioritising and quality assurance of National Clinical Audits so as to recommend their endorsement by the Minister for Health. The NCEC Framework for Endorsement of National Clinical Audit (Oct 2015)³ outlines the criteria and procedures for this process. The criteria are based on internationally recognised principles and best practice for audit. The vision is that there will be a suite of NCEC National Clinical Audits that are mandated as high quality and high priority for the Irish health system. So not all clinical audits will become NCEC National Clinical Audits, nor is it appropriate for all to do so. However, the principles of audit, as outlined by the NCEC, should transcend the multiple levels of clinical audit activity in the health system. The NCEC role is also to align National Clinical Audit with implementation levers such as the Department of Health’s legislative programme. To this end, the forthcoming Health Information and Patient Safety Bill and the Patient

² Please see appendix 1 for further details.

³ <http://health.gov.ie/wp-content/uploads/2015/12/Framework-for-Endorsement-of-National-Clinical-Audit.pdf>

Safety Licensing Bill will encourage and support the practice of clinical audit as part of quality improvement and clinical governance mechanisms to enhance patient safety.

- **The National Office for Clinical Audit (NOCA).** NOCA was established in 2012 to create sustainable clinical audit programmes at national level. NOCA supports hospitals to learn from their audit cycles. NOCA is funded by the HSE QID. NOCA is supported by the Royal College of Surgeons in Ireland (RCSI). The NOCA Governance Board is an independent voluntary board convened to guide the clinical decision making and strategic direction of NOCA.
- **RCPI Specialist Quality Improvement (SQI) Programmes** include SQI's related to histopathology, radiology and endoscopy. These programmes are funded by the QID, and governed by a multidisciplinary steering committee. Their work includes developing clinical guidelines related to the SQI, and supporting audit of compliance with these guidelines.
- **Other agencies that support/conduct audit within the HSE** include the Integrated Clinical Programmes; the National Perinatal Epidemiology Centre (NPEC); and the Maternal Death Enquiry (MDE).

Independence and impartiality

It is important at this juncture to consider notions of independence, impartiality and integrity.

- Impartiality is defined as: *“evenhandedness” or “fair-mindedness”. “It is a principle of justice holding that decisions should be based on objective criteria, rather than on the basis of bias, prejudice, or preferring the benefit to one person or another for improper reasons”.*
- Independence is defined as: *“Free from the control or influence of others; not connected with another, separate”.*
- Integrity is defined as: *“The quality of being honest, fair, and good; The state of being whole or unified”.*

There was a perception revealed at interviews that auditor independence is correlated to audit integrity. As seen above, independence refers to an individuals' freedom from the control or influence of others. Independence does not guarantee freedom from the control and influence of individual internal human factors such as *“bias”*. Bias is a powerful phenomenon. Few, if any, are immune to it. Its insidiousness is caused by the fact that we tend not to be

aware of its presence within us nor of its hold upon us. It is the single most commonly cited factor in the literature that has been identified to detract from data quality, impartiality and integrity. Fortunately, the integrity and impartiality of data is measurable in terms of data validity and reliability. It is important not to make the assumption that independence guarantees audit integrity. It is also important to recognise the high level of integrity associated with data generated from Healthcare Audits to-date. Finally, it is important to continuously enhance methods of measuring the quality and integrity of audit data for assurance and quality improvement purposes.

Integrity of data for quality assurance and improvement purposes

Currently, the level of assurance provided by the types of audit conducted is based on the relative or perceived levels of independence of the particular agencies conducting the audits. As stated previously, what is most important in terms of providing real assurance is the integrity of the data produced by audits for assurance and organisational improvement purposes. This is as important for local clinical audit as it is for national audits. Fortunately, data integrity is objectively measurable in terms of data validity, reliability and generalisability and it is proposed that all audits conducted within the HSE whether locally, nationally, or by external agencies – should be quality assured to ensure that they satisfy the following audit quality criteria:

- *Validity*: Valid audits are audits that ask all the questions they need to ask, and get all the answers they need to get to identify non-compliance, and solutions to address non-compliance (i.e. recommendations).
- *Reliability*: Reliability refers to whether repeated efforts to measure the same phenomenon come up with the same answer. Therefore, reliable audits are audits that identify non-compliance correctly, and the solutions to address the non-compliance correctly. This means that if another audit team were to conduct a second audit of the same issues using a comparable methodology, they would not identify any different or other non-compliance issues, or recommendations.
- *Generalisable*: Generalisability refers to the extent to which the findings of the enquiry are more generally applicable outside the specifics of the situation studied. The generalisability of audits refers to the ability of an audit of a specific site, or a number of sites, to identify non-compliance issues, and solutions (i.e. recommendations) that

are applicable to the wider health system outside of the site(s) where the audit occurred.

- *Timely*: Timely audits are audits which are completed to an acceptable standard in as short a timeframe as is reasonably practicable. Delivering audits in a timely manner means that the organisation gets assurance and/or the opportunity to address non-compliance and related quality and safety improvement as early as possible.
- *Fair*: Fair is defined in the Oxford English Dictionary as being just, fair-minded, open minded, honest, upright, honourable, trustworthy, unbiased, unprejudiced, impartial and neutral. To ensure impartiality and fairness - those whose services/actions are reflected in an audit report must be given an opportunity to check relevant drafts so that they have an opportunity to give feedback to ensure that the final report is as factually and technically accurate, impartial and fair as possible.
- *Accurate*: Accurate is defined as correct in all details; faithfully or fairly representing the truth. It is important for audits to be accurate. If they are not accurate, they are unlikely to give correct assurance and/or identify correct opportunities for quality and safety improvement as well as this is possible.
- *Instil confidence*: It is important that service users, the staff and managers in services that are audited, the HSE, external stakeholders, and the public - have confidence that audits have correctly identified all relevant non-compliance issues, and recommendations to address these as well as this is possible.

National audit within NHS Scotland.

The Associate Director (Consultancy, Knowledge & Research Services) in the Public Health & Intelligence Unit within NHS National Services, Scotland, advised that there is a National Clinical Outcomes and Measurement for Quality Improvement Group that sits within the Quality Strategy Section of the Scottish Government. This group focuses on quality policy, and collecting data for improvement and includes a significant National Audit Programme. It links with NHS England who have an English Programme for National Audit. Their purpose is to achieve internationally recognised Health Intelligence Services. The National Audits that are conducted have emerged from the following:

- Clinicians requests for national audits
- Media interest in specific issues
- The need to monitor status/improvement

There is a plan to conduct more “*Snap Audits*”. As audits are repeated, the gap in compliance is improving and there are fewer gains to be made from repeating audits, so that audit resources need to be diverted to other areas of greater audit need. NHS Scotland is currently considering the process for this.

Strategic partnerships have been created with the Institute for Healthcare Improvement (IHI) in relation to implementation science and how to bring implementation science into the audit process. Similarly, NHS Scotland is exploring the implementation of Human Factors Science in relation to enhancing understanding of the Human Factors causes of non-compliance identified in audits.

There is a wide range of audits currently underway including audits of the following:

- The Global Waiting System
- Musculoskeletal Access
- Scottish Arthroplasty Audit
- ICU Audit
- Multiplesclerosis Register
- Renal Register
- Stroke Care Audit.

The above reflects an audit programme that is more in line with National Clinical Audits as conducted by NOCA than it is in line with the programme of both clinical and non-clinical audits that cross both acute and community service as conducted by the Healthcare Audit Function.

There is a Forum between NHS England, Northern Ireland, Scotland and Wales which focuses on sharing learning on collecting data for improvement and NHS Scotland indicated that they would be interested in collaborating with the HSE generally and also by inviting the HSE to engage in this Forum.

National audit within NHS England.

The Healthcare Quality Improvement Partnership (HQIP) in England advised that the National Clinical Audit and Patient Outcomes Programme within NHS England supports 30 National Audits supported by HQIP on behalf of NHS England and devolved nations. These national clinical audits address a range of priorities (i.e. diabetes and cancer) across primary and secondary care. HQIP aims to improve health outcomes by enabling those who commission, deliver and receive healthcare to measure and improve healthcare services. HQIP published guidance for national audit reports “*Reporting for Impact*” in March 2016 suggesting a framework for audit reports. This covered issues such as defining target audiences, writing audit summaries, presentation of findings in multiple formats, and dissemination.

An assessment of national audits is currently underway in NHS Scotland and England.

Appendix 1: Table showing details of various HSE agencies that conduct Audit within the HSE with a list of external agencies that may undertake audits within the HSE.

	Quality Assurance and Verification Division Healthcare Audit Team	HSE Internal Audit	Quality Improvement Division (QID) Support local Clinical Audit	QID/RCPI Specialist Quality Improvement (SQI) Programme Audit	National Office for Clinical Audit (NOCA)	External Regulators (i.e. HIQA, C&AG) ⁴
Established	2010	2005 from individual IA functions within individual Health Boards	2014	Histopathology 2009 Radiology 2010 Endoscopy 2011	2012	Various
Governance	Reports to National Director, QAVD; Provides assurance to HSE Risk Committee	Audit Committee (and Risk Committee for risk issues identified in IA reports).	QID	Funded by HSE QID Governed by Multidisciplinary Steering Committee chaired by HSE QID	Funded by QID Independent Voluntary Board	Various
Resources	Team of 13 staff comprising AND, GMs, Grade VII's & and Grade V staff. 6 currently in recruitment. Business case for additional 12 staff (6 in 2018 and 6 in 2019) approved in principal by the HSE Risk Committee.	48 staff	1 WTE	Currently 4. Plan for 5, including Programme Managers plus technical analysts. HSE has provided additional resources at audit sites to collect and input data.	Operationally supported by the RCSI. 10 full time staff and 2 part-time seconded nurses. HSE has provided additional resources at audit sites to collect and input data.	Various
Purposes	Provides assurance to HSE Risk Committee of HSE compliance with legislation and PPPG's (excl financial), and contributes to QI.	Give assurance of compliance with governance, financial and operational policies, procedures and standards	Training and support to local staff wishing to carry out level 1 clinical audits.	To drive improvement in SQI areas.	Designs, establishes and supports a portfolio of national clinical audits based on national priorities.	Various
Governing regulations, standards, PPPG's.	Legislation (excluding financial), Standards, PPPG's related to the delivery of health services	Financial legislation and standards	HSE Practical Guide to Clinical Audit (2013)	MOU; Information Governance Policy; Guidelines; ToR	Clinical Guidelines/standards of best practice for all audits; NCEC Endorsement; Data Protection/ HIQA Information Standards	Various
Scope	All parts of the HSE	All parts of the HSE	Clinical Audit within all parts of the HSE	Scope is the 3 SQI Areas of histopathology, radiology and endoscopy.	National Clinical audits across the Healthcare System.	Various
Type of audits	Clinical and Non-clinical	Financial Audit	Clinical audits; Refers to broader healthcare audits.	Clinical audits.	National Clinical Audits	Various
Process for scheduling/prioritising audits	Under review; Currently, requested by Risk Committee, National Directors and NPSO	Annual audit planning process, controls assurance gaps, risks, requests, and emerging concerns.	Do not schedule or prioritise audits. Local areas do this.	Annually, or when there is readiness for audit in the context of the overall SQI work.	Under review ⁵ . Currently inherit existing audits/ registers, requests from Clinical Programmes / Clinicians	Various
Level of assurance provided	Level 3	Level 3	Level 2 when local staff who are trained conduct local clinical audit.	Level of assurance for SQI Audit not referred to in the HSE Controls Assurance Framework. SQI audit is a quality improvement activity.	Level of assurance for NOCA Audit not referred to in the HSE Controls Assurance Framework. NOCA Audit is a quality improvement activity.	Level 3
Audits	Approximately 15 national	158 Internal Audit Reports	N/A. 1,300 staff trained.	5	6 audits fully implemented with	Various

⁴ A list of the external agencies that may conduct audit within the HSE is included on the following page.

⁵ Alignment with HSE priorities; Impact and value for money; Need; Professional and Patient Care Support; Alignment with other national activities.

completed	summary audits and 90 site audits per year	were issued in 2016.	Audit tools developed for all areas of Nursing, medical, AHPs across all divisions		ongoing annual reports. 2 in implementation to end 2018. Considering additional audits.	
Audits published	Approximately 15 summary national audits per year since 2013.	Reports released under FOI every 6 months.	N/A	4 x annual histopathology National Data Reports; 1 x annual National Data Report for endoscopy; Fist radiology report due in coming years	6 annual national reports. Commence summary reports for public & patients in 2017.	Various

List of external agencies and regulators that may undertake audits within the HSE (This may not be an exhaustive list):

- 1) Comptroller & Auditor General (C&AG)
- 2) Data Protection Commissioner
- 3) Dental Council of Ireland
- 4) Environmental Protection Agency (EPA)
- 5) Food Safety Authority of Ireland (FSAI)
- 6) Health and Social Care Professionals Council
- 7) Health Information & Quality Authority (HIQA)
- 8) Health Products Regulatory Authority (HPRA)
- 9) Irish Blood Transfusion Service (IBTS)
- 10) Irish Medical Council (IMC)
- 11) Medical Exposure Radiation Unit (MERU)
- 12) Mental Health Commission (MHC)
- 13) National Disability Authority (NDA)
- 14) National Haemophilia Council
- 15) Nursing and Midwifery Board of Ireland (NMBI)
- 16) Pharmaceutical Society of Ireland (PSOI)

Appendix 2: Recommendations with expanded details.

No	Detail
1	Actively engage service users/patients in the process for prioritising and scheduling Healthcare Audits, and in the conduct of individual Healthcare Audits.
2	<p>Develop and implement a process of prioritising and scheduling audits based on the following:</p> <ol style="list-style-type: none"> a) Gaps in the controls assurance process b) Themes from incident and complaints analysis c) Risk d) Cross service issues (all audits should go across services except in exceptional circumstances) e) Issues that affect greatest number of service users f) Issues that are of the most importance to service users g) Audits that build on local audits (i.e. testing/validation of local audit findings) h) Some special requests if resources are available (i.e. from national and local requesters). i) Unscheduled audits in response to emerging evidence based safety concerns by the public and/or staff j) Audits where service user/staff voice and engagement in audits is possible (i.e. 360° audit)
3	Continue to improve Healthcare Audits methods to enhance data integrity and usefulness, including enhancing capability and capacity for sampling, use and development of ICT tools and platforms, and statistical analysis.
4	Increase the number and organisation-wide coverage of Healthcare Audits.
5	Develop capacity for rapid audit response to emerging safety concerns.
6	Develop and implement a process for tracking implementation of audit recommendations and linking audits to specific quality improvements. This should include the development of KPI's equivalent to the KPI's related to the implementation of Internal Audit recommendations whereby 75% of recommendations that are risk rated as high or medium must be implemented within 6 months, and 95% should be implemented within 12 months.
7	Delivery of training and support to build the capacity for local Healthcare Audit enabling more sophisticated national audit including testing and validation of local audit findings by HCA.
8	Enhance the profile of the HCA function within the HSE and amongst stakeholders through publication of reports, the use of the internet and E-zines, and presentations and attendance at conferences. It will be important in this to convey clearly the purpose of HCA to address the confusion about whether it is about assurance or quality improvement. It should be stated emphatically that the purpose of HCA is to contribute both to assurance and quality improvement as compliance with evidence based PPPG's is related to improved quality. The work to improve the profile of HCA should be exploited as an opportunity to share learning from HCA work.
9	<p>To have a national strategic approach to audit that would address the problem of fragmentation, omissions and overlaps in audit work. It is recognised that there are many stakeholders in this in addition to the Healthcare Audit function and also that much of this is outside the control of the Healthcare Audit function. For their part, in the interim, it is recommended that the HCA function develop their own strategy that should eventually be aligned with any National Audit Strategy that may be developed.</p> <p>Healthcare Audit Strategy</p> <p>Develop and implement a 3 year HSE Healthcare Audit Strategy</p> <p>National Audit Strategy</p> <p>Develop and implement a national audit strategy and framework for the HSE which includes a cohesive National Audit Plan requiring clarifying the roles of the various audit agencies to prevent overlaps and omissions in audit work. This strategy should include mechanisms for evaluating the quality of audits that consider the validity, reliability and generalisability of audit data; and the National Clinical Excellence Committee tools for quality assuring audits.</p>