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Clinical Audit Policy & Procedure

Author & Title	Clinical Audit Policy. Trevor Smith (Head of Clinical Audit and Effectiveness). Dr Melanie Maxwell Senior Associate Medical Director
Responsible dept / director:	Office of the Medical Director. Dr David Fearnley Executive Medical Director
Approved by:	Quality, Safety and Patient Experience Committee
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First operational:					
Previously reviewed:					
Changes made yes/no:					

N.B. Staff should be discouraged from printing this document. This is to avoid the risk of out of date printed versions of the document. The Intranet should be referred to for the current version of the document`

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1. Introduction / Overview:

1.2 Clinical Audit:

Clinical audit is a multi-professional, multidisciplinary activity.

"Audit is not concerned primarily with fault or discrepancy finding, but with the examination of working practice to improve effectiveness". Dickens (1994)

Figure 1 The Clinical Audit Cycle

"*Clinical audit is a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes.*"

New Principles of Best Practice in Clinical Audit (HQIP, January 2011).

Within the Health Board clinical audit is embedded within the future direction of improvement activity. Audit is a tool within the quality framework, identifying and prioritising improvement activities (Quality Planning) and providing assurance about service quality (Quality Control):

Figure 2: Quality Cycle: based on Juran and Godfrey (1999).

2. Policy Statement

This policy is applicable across all services participating in clinical audit within the Health Board. It sets out the expectations of the Health Board with respect to audit planning, multidisciplinary participation, and acting on the audit findings to maximize its effectiveness.

Clinical audit planning prioritises externally mandated requirements (as documented in the annual *National Clinical Audit and Outcome Review Plan* from Welsh Government), as well as local priorities in line with the Health Board's strategic objectives and risks.
Services should consider audits that provide information and/or assurance relating to key risks and strategies, such as the quality improvement strategy, and other service improvement activity relevant to the Health Board's priorities using the agreed tier structure (see section 8.1).

3. Aims / Purpose

This policy aims to support a culture of best practice in the management and delivery of clinical audit.
The purpose of this policy is to set out the rationale for clinical audit and provide a framework for such activity, including standards, guidance and procedures.

4. Objectives

This policy outlines processes in relation to clinical audit activity within BCUHB. It will reinforce its role within the quality framework in delivering quality improvement and quality control.

This includes:

- Topic selection based upon priorities (national and local).
- Local governance arrangements
- Clinical audit and effectiveness training
- Patient and carer involvement
- Roles and responsibilities
- Assurance about the effectiveness of services in relation to best practice

5. Scope

This policy relates to all BCUHB staff (including students and volunteers) and partner organisations participating in clinical audit activity within BCUHB; either by professional requirement, individual interest or relevance to a specific pathway / care group. This policy is also applicable when BCUHB is working in partnership with other health and social care partners. Where BCUHB commissions activity externally, quality assurance including participation in audit, is included within the contractual arrangements.

6. Roles and Responsibilities

6.1 Chief Executive Officer (CEO)

The Chief Executive Officer has overall responsibility in relation to the statutory duty for quality within the organisation and for participation in the mandatory requirements for clinical audit participation, as set out within the Welsh Government's *National Clinical Audit and Outcome Review Plan (NCAORP).*

6.2 Executive Medical Director

The Executive Medical Director is the Executive lead for clinical audit and effectiveness activity; ensuring that the BCUHB audit plan aligns with mandatory requirements, organisational priorities and is supported across all clinical services including primary, community and secondary care. The Clinical Effectiveness Department is located within the Office of the Medical Director.

6.3 Professional Leadership Roles

This group includes other clinical executives, medical directors, nursing directors and other clinical leaders, including clinical audit leads where they exist. Staff in these roles will support the implementation of this policy for services that fall within their remit and sphere of influence.

6.4 Lead Auditors

Lead auditors are responsible for individual audits. They will ensure the clinical audit cycle is completed in line with their service's clinical audit annual plan. This will include data collection, discussion of the findings and development and delivery of the action plan to improve care. It is their responsibility to escalate any delays or concerns through the service's governance framework.

6.6 Other Staff

All staff have a duty to ensure they are providing effective care to deliver best outcomes for patients. Participation in relevant clinical audit to enable benchmarking against key standards, supporting the development of subsequent action plans and undertaking quality improvement activity is expected.

6.7 Clinical Effectiveness Department

The department's role is managing the audit process. This includes working with services to develop the annual clinical audit plan, maintaining a central repository of audit activity, monitoring the timely implementation of the plan and delivering assurance reports to relevant governance groups culminating in an annual clinical audit report.

The department will provide proportionate support to BCUHB staff for all stages of the clinical audit cycle; priority is given to the mandatory audits (national or local).

The department delivers ad hoc audit and effectiveness training (see section 11).

7.0 Groups / Committees

The following Groups / Committees have a role in ensuring that clinical audit activity within their remit is optimised in terms of improvement potential and assurance. This will include approval, reporting and monitoring as relevant to each group's terms of reference. (See Appendix 1 – governance structure)

7.1 Audit Committee

The Audit Committee is the approving committee for the annual plan (national and locally prioritised audits). It will seek assurance on the overall plan, its fitness for purpose and its delivery. The role of the Audit Committee includes seeking assurance on:

- Does the organisation have a plan - and is it fit for purpose?
- Is it completed on time?
- Does it cover all relevant issues?
- Is it making a difference and leading to demonstrable change?
- Is change supported by recognised improvement methodologies?
- Does the organisation support clinical audit effectively?

7.2 Quality, Safety and Experience Committee (QSE)

The Quality, Safety and Experience Committee requires more detailed assurance that clinical audit is supporting the delivery of effective health care. It requires assurance that clinical audit is used to identify areas for improvement and subsequent actions deliver better outcomes for patients.

QSE will receive the clinical audit annual plan and recommend its adoption to the Audit Committee. It will be the approving committee for the Clinical Audit Policy and Procedure.

7.3 Joint Audit & Quality Committee

This committee meets annually. It includes all members of the Quality, Safety and Experience Committee and Audit Committee. Its purpose is to jointly review the effectiveness of clinical audit and receive the annual audit report.

7.4 Quality and Safety Groups

At each level of service e.g. Corporate/Divisional/ Site there are quality and safety groups. These groups ensure there is an effective audit function, supporting quality planning and assurance. Risks identified through the clinical audit process and outcome will be considered, mitigated and/or escalated from sites and divisions to the corporate group as appropriate.

7.5 Clinical Effectiveness Group (CEG)

CEG provides a forum where clinical audit and service evaluation is discussed as a standard agenda item. In relation to clinical audit, CEG receives exception reporting from a number of effectiveness-related groups including the Clinical Improvement and Audit Groups or equivalent Quality and Safety Groups. This group will receive quarterly progress reports and the annual report; escalating risks in line with the governance framework.

8.0 Registration of audits:

All clinical audit activity within the Health Board should be prioritised to ensure it aligns with strategic or operational priorities as outlined in the service or corporate annual clinical audit plan.

All local clinical audit projects conducted within the Health Board must be approved prior to registration, either by the relevant Quality & Safety Group or Clinical Lead, in advance of registration with the Clinical Effectiveness department.

There is a clearly defined application procedure for registration, which involves the following steps:

8.1 Registration Tiers within BCUHB

Tier 1: National "must do" audits. These clinical audits are mandated by Welsh Government or other regulatory bodies such as *Medicines & Healthcare products Regulatory Agency* (MHRA). Local available resources are prioritised to support these audits. Nationally mandated audits require the completion of the assurance proforma to be returned to Welsh Government within 4 weeks. This documents the actions being taken to address the audit report findings.
NB: All National Clinical Audit and Outcome Review Plan (NCAORP) projects must be incorporated within relevant Divisional/Directorate annual clinical audit plans.

Tier 2: Local priority audits: These 'local must do' audits support delivery of the Quality Improvement Strategy goals and priorities, including accreditation requirements specific to the service, NICE guidance compliance, safety audits, audit related to high risk activity and corporately agreed service improvement priorities. These audits will take priority over completing tier 3 audits.
NB: All Corporate projects agreed at BCUHB Quality & Safety Group as priorities must be incorporated within relevant Division/Directorate annual clinical audit plans.

Tier 3: Local audits. This activity relates to those audits that have been agreed by the Division/Directorate to be included within their local, annual forward plan for clinical audit activity (see section 8.3 below). These should be risk based. All Tier 3 projects must:

- be approved by their Divisional/Directorate or Primary Care Lead. *(NB: These should not be approved unless there is local capacity and completion will not detract from completing Tier 1& 2 audits, including the associated improvement work.)*
- be registered with the Clinical Effectiveness Department accessed through a self-registration audit tool for registering Tier 3 has been developed. . To register your audit click on the link below:

http://7a1a1srvinforep/Tier3ClinicalAuditProjectSubmission2/ClinicalAuditProjectEformModelsRegisters/AboutUs

NB: It is recognised that tier 3 audits may be undertaken as part of education and/or training, to learn the methodology. However, they should still be subject to completion of the audit cycle.

Quality improvement projects may use audit as a tool for measurement; however, they fall outside the scope of this policy. Quality improvement projects should be registered on the quality improvement hub (https://www.bcuqi.cymru)

8.2 Clinical Effectiveness Department Registration Database

All approved projects are allocated a unique ID number. A database is held within the Clinical Effectiveness Department, storing all Health Board registered clinical audits/ service evaluations. This facilitates audit activity reporting, identifies potential re-audits and provides evidence to support reviews and Health Board-wide comparison of findings. It enables quality planning and identification of quality improvement projects to support reliable care.

8.3 Annual Divisional / Directorate Clinical Audit Plan

An annual clinical audit plan will be agreed within each Division/Directorate including Primary Care and Community Services by the end of January. Early allocation of suitable lead auditors and the resources including clinicians' time required to complete the audit will optimise completion of the plan.

A systematic approach which enables the multidisciplinary team to prioritise and agree upon topics for inclusion is recommended with domains including:

- ***Frequency*** ('how often' or 'how many'?)
- ***Degree of risk*** (likelihood of something going wrong or not being done).
- ***Level of concern*** (how important is the question?)
- ***Outcome*** (what is the impact in relation to potential for improvement/harm?)

(Welsh Assembly Government, 2003)

8.4 Corporate Clinical Audit Annual Plan

The corporate clinical audit annual plan will be agreed by the end of February each year. This will include all identified tier 1 and tier 2 audits.
Tier 1 audits will capture in-year data collection and/ or review of report and action planning. Some audit reports will be an analysis of historic data, usually from the previous year.
Tier 2 audits will be based on audits identified by the Clinical Executive Leads as well as Divisional Management teams in line with section 8.1 above.

8.5 Clinical Effectiveness Department Support

The Clinical Effectiveness Department is resourced to support Tier 1 and Tier 2 activity. Tier 1 activity will be prioritised.

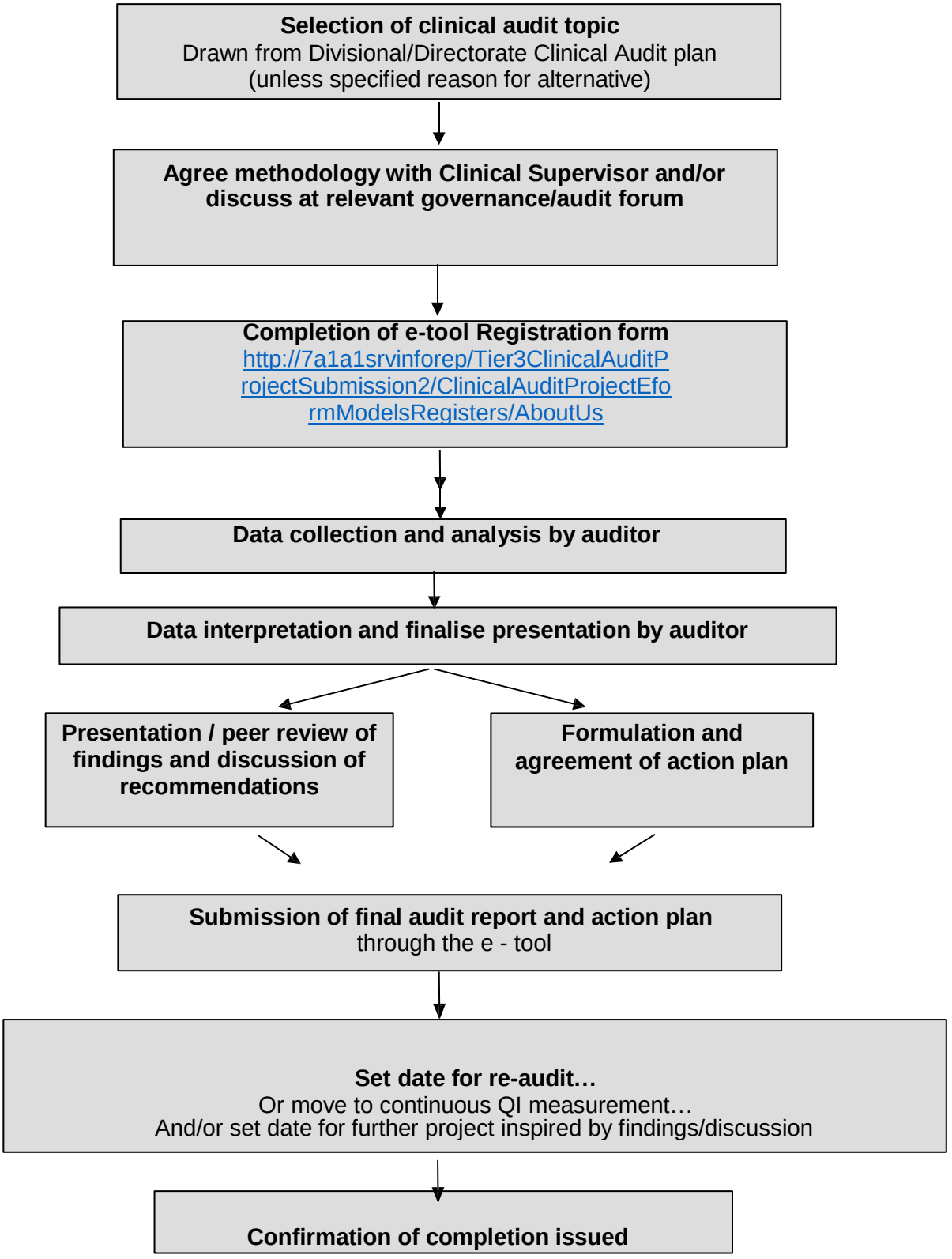
Clinical Audit Facilitator staff will meet with lead auditor(s) to assess the level of support they require and to:

- Identify potential for patient participation/involvement.
- Identify potential for multidisciplinary participation/involvement.
- Agree the proposed methodology.
- Assist/advise with identification of evidence-base/critical appraisal.
- Assist with construction of clear and measurable audit standards.
- Agree data collection pro-forma/questionnaire format.
- Confirm local management support.
- Confirm the appropriate Divisional/Directorate clinical lead is aware of the project.
- Agree project timescales (including planned presentation date).
- Ensure Welsh Government assurance proformas are completed in a timely manner.

8.6 Assurance Reporting

The Clinical Effectiveness department will produce quarterly annual plan monitoring reports for the Clinical Effectiveness Group. These reports will be cumulative, building to an annual report that will be received by the Joint Audit & Quality Committee in November each year. The report will document progress against the plan and highlight key service improvements related to clinical audit activity.

9. Procedure - Figure 1: Algorithm displaying clinical audit Tier 3 registration and progression



10. Developing a Clinical Audit Project

The process for clinical audit project development, registration and progression are displayed in algorithm format above.

10.1 Selection of topic

The Divisional / Directorate Annual Clinical Audit plan identifies the topics for Supervisors advising their trainees, juniors and other colleagues. Staff contacting Clinical Effectiveness department for advice will also be directed to these plans and the relevant Clinical Lead for their clinical area.

10.2 Multidisciplinary audit

Clinical Leads and lead auditors will assess all audits in relation to their potential for multidisciplinary and multi-professional involvement. Consultation with all relevant staff groups will occur. Where applicable, the lead auditor will be advised to invite participation from colleagues representing other professionals appropriate to the topic and also consider Managed Clinical Services colleagues such as Radiology and Pathology.

Multidisciplinary audit refers to a clinical audit team composed of representatives from at least two different disciplines (ideally those associated with the episode of care being audited).

10.3 Patient and Public Involvement

In planning each audit the potential for service user, carer and/or public involvement should be assessed and promoted. This may involve communication with appropriate forums relevant to the topic and/or the service to achieve this. This would range from gaining feedback regarding the proposed audit pro-forma/questionnaire to direct involvement where possible with other stages of the audit, guided by the relevant Information Governance considerations.

10.4 Presentation / dissemination / feedback

All lead auditors will feedback their findings to the relevant service forum, where peer review will confirm that the findings are clinically robust. In addition, findings will be shared as widely amongst the Health Board as appropriate to the topic.
Auditors will agree, in discussion with their Clinical Lead, the appropriate venue for PowerPoint style presentation (see Appendix 2 - template) and efficacy of utilising other media options (poster, circulation of brief written report, intranet, etc.).

10.5 Action planning

Where recommendations are made as a result of the audit, an action plan must be developed following consultation with the relevant staff (ideally at a service forum). Peer review will ensure that findings are disseminated and ascertain whether the recommendations are robust. The action plan must be specific, objective, set within measurable timescales and accountable in relation to who is responsible for each action. (See appendix 3 - action plan template). Tier 1 audits require the completion of the assurance proforma (Part A&B) within 4 weeks of the report release; this documents the actions being taken in response to the audit findings nationally and locally.

10.6 Submission of Clinical Audit Report

On completion of the audit, the lead auditor is required to provide the Clinical Effectiveness department with a copy of the final report and action plan (see Appendix 4 – report template).

10.7 Re-audit

Re-audit is not always necessary. For example, if no improvement needs have been identified or there is an alternative methodology to ensure improvement. In the latter case, it is important that all recommendations are tracked and monitored through the appropriate committee. Where assurance is required through audit, this needs to be included within a future clinical audit annual plan.

10.8 Letter of Completion for Project Lead

On receipt of the final report, the lead auditor/team (who demonstrate direct contribution) will be issued with a letter confirming their participation by the Clinical Effectiveness department.

10.9 Assurance

The Clinical Effectiveness department will be responsible for:

- Collating the annual corporate clinical audit plan each new financial year,
- Providing the Quality, Safety and Experience Committee with cumulative quarterly reports leading to an annual report that monitors progress against the plan.
- Providing JAQS with an annual report against plan.

11. Equality, including Welsh Language

Betsi Cadwaladr University Health Board is committed to advancing equality and protecting and promoting the rights of everybody to achieve better outcomes for all. The legislative framework requires us to promote equality in everything that we do.

Clinical audit activity should be undertaken with regard to equality and inclusion and opportunities to advance equality optimised. The process for determining choice of clinical audit projects, and identifying service user samples, must be inclusive and representative of the total population and where relevant consider protected characteristics of: age, disability, gender reassignment, race, religion/belief, gender, sexual orientation, marriage/civil partnership, pregnancy/maternity.

An Equality Impact Assessment (EqIA) for this policy has been completed.

12. Training

All staff participating in clinical audit activity should have a good understanding of this methodology. There is an 'e' learning training session provided by HQIP which is accessible through the BCUHB intranet site: *(https://www.bcuqi.cymru)*

In addition, the Clinical Effectiveness Department will respond to requests to provide face-to-face sessions for teams where this can be delivered within capacity.

13. Review

The Clinical Audit Policy, as a new policy will be reviewed in one year's time and then on a three year cycle.

14. References

DICKENS, P. (1994). In: Welsh Assembly Government. (2003). *An introduction to clinical audit.* Wales

Healthcare Quality Improvement Partnership (HQIP). (2011). *New Principles of Best Practice in Clinical Audit.*

JURAN, J.M., GODFREY, A.B. (eds). (1999). *Juran's Quality Handbook.* 5th Edition. New York: McGraw Hill.

Welsh Assembly Government. (2003). *An Introduction to Clinical Audit*. Wales.

Appendix 1: Governance

NB: Quality governance structures are currently under review and this will be amended once agreed**.**

Appendix 2: Template for PowerPoint presentation slides.

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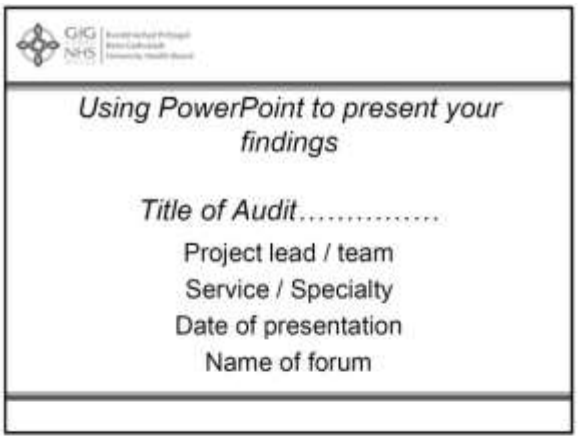

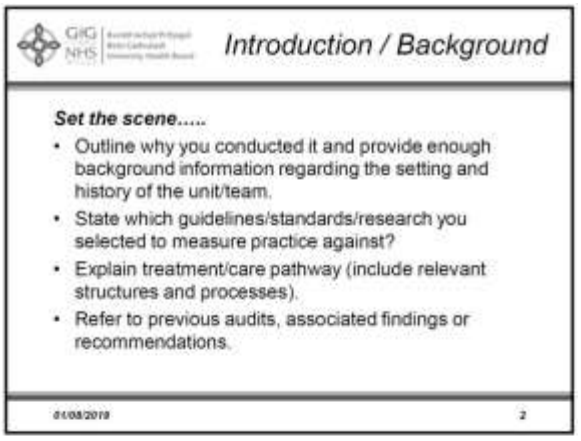

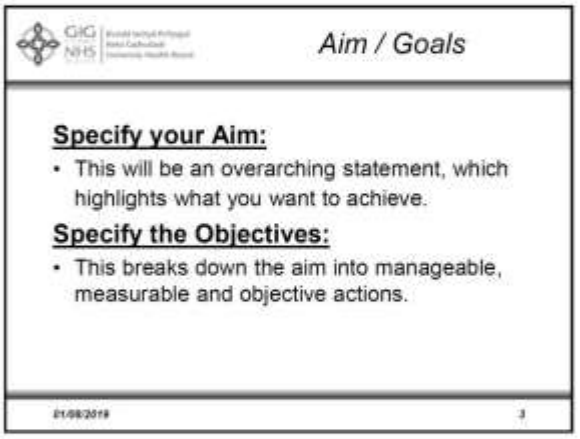

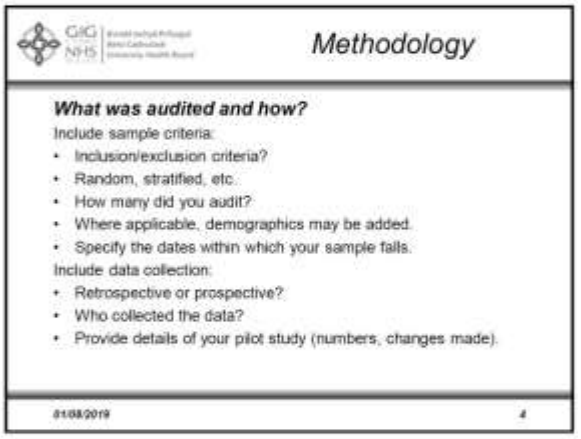

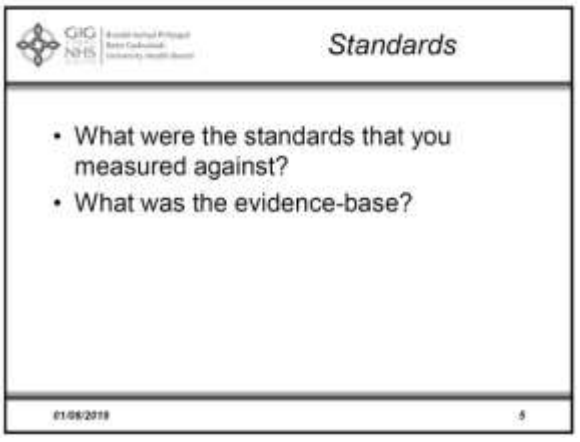

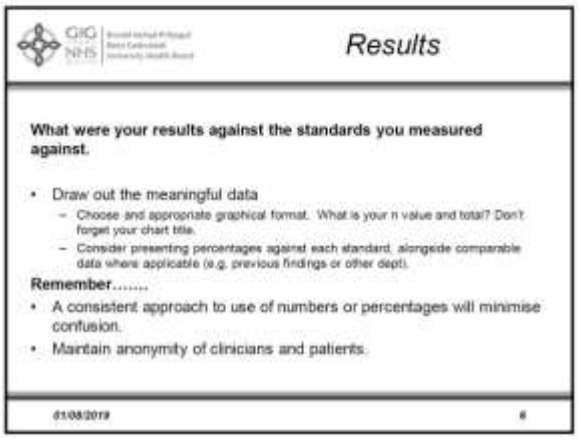

Conclusions

- Please highlight problem areas, improvement needs and any areas of good practice.
- Draw together your findings, highlighting main points for discussion and action.

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Recommendations / Action Plan

What now?

Include

Recommendations and relate back to your audit standards.

- Where were these discussed (forum).

Describe your action plan.

- Specify who is responsible for each action – ensure that they agree to this!
- Set timescales and review dates (if applicable) for each action.
- Make actions realistic and achievable.

Date for re-audit (if appropriate).

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Next steps

After presenting your findings:

Communication is key.

- Agree:
  - action plan following peer review discussion.
  - review date to monitor actions.
  - Re-audit date.
  - Consider: continuous measurement, research or other QI methodology (as appropriate).
- Ensure handover of actions to willing colleague if leaving.
- Agree on appropriate further dissemination of results to MDT colleagues.

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Appendix 3: Action planning template

Title			
Lead Auditor		**Author:**	
Contributors			
Approving Committee		**Date:**	
Is this on the risk register		**If yes, Score:**	

Action Plan:
(Please complete the action plan to specify how improvements will be made - i.e. what will be done, when and by whom?)

Issue Identified	**Improvement Action**	**By Who**	**By When**
Re-audit:	Date:	By Whom:	

Appendix 4: Template for final Clinical Audit report

Use attached guidance sheet: "Using Template Format for Clinical Audit Report".

Auditor (person conducting audit):	**Audit No:**	**Date:**
Audit Team members:	**Speciality / Service:**	

Full title of clinical audit project:
Include enough information to make the topic and location clear.

Introduction / background:
Set the scene for your audit. Outline why you conducted it and provide the reader with enough background information to understand the setting and history of the unit/team.

- What are the reasons for selecting this topic?
- Which guidelines/standards did you select to measure practice against?
- Refer to and summarise any relevant research or other forms of evidence.
- Outline topic-specific information and explain abbreviations or specialised terminology.
- Explain treatment/care pathway (including relevant structures and processes).
- Refer to previous audits and associated findings or recommendations.

Specify Aim:
This will be an overarching statement, which highlights what you want to achieve.
Specify Objectives:
This breaks down the aim into manageable, measurable and objective actions.

Standards:
What were the standards that you measured against – what was the evidence-base?

Methodology:
Explain the audit methodology you used, including sample criteria, time period and data sources used (i.e. what was audited and how?)

This section is important as it needs to make explicit the *'who, how, when and where'* elements of your project procedure. As in a scientific report, it is important that anyone wanting to replicate your project can do so by following your methodology.

The sample:

- Were there any inclusion/exclusion criteria?
- How was your sample selected? - random, stratified, etc.
- How did you identify participants? - Information Dept, admission book, etc.
- How many did you audit?
- If cases were missing - specify why (e.g. notes missing).
- Where applicable, demographics may be added (either here or in your results section)
- Specify the dates within which your sample falls.

The data collection:

- Was your data collection retrospective or prospective?
- Who collected the data?
- When were pro-forma/questionnaires completed/returned?

The pilot:

- Provide details of your pilot study (numbers, changes made).

Did you include your pilot data in your final analysis? If not, outline reason (e.g. data items changed significantly following pilot).

Results:
Provide the results of audit against the standards that you were measuring against and also any supporting or additional information. *Table format provided below*.

- Present only results that relate to the audit criteria.
- Don't be tempted to flood the reader with unnecessary data. The clarity of the point you are trying to communicate may be lost.
- Follow a logical order and grouping of results (such as the care pathway).
- Draw out the meaningful data and present in an accessible and graphical format (where applicable).
- Ensure all charts and tables are titled and state the 'n value' (total number 'out of').
- State how the data was stored and analysed (such as Excel or SPSS).
- It may be useful to use a table to present percentages against each standard, alongside comparable data where applicable (e.g. previous findings or other dept).
- A consistent approach to use of numbers or percentages will minimise confusion.
- Maintain anonymity of clinicians and patients.
- Use objective statements and avoid subjectivity.

No.	Standard	% Achieved	% Not Achieved
1.			
2.			
3.etc.			

Conclusions:
Please highlight problem areas, improvement needs and any areas of good practice.
Draw together your findings, highlighting main points for discussion and action.

Recommendations:
Clearly state your recommendations and relate back to your audit standards.

Action Plan:
Please complete the action plan to specify how improvements will be made - i.e. what will be done, when and by whom?
Complete the action plan to specify how improvements will be made (i.e. what will be done, when and by whom).
Following discussion of the recommendations at the appropriate forum, construct an action plan.

- Specify who is responsible for each action – ensure that they agree to this!
- Set timescales and review dates (if applicable) for each action.
- Make actions realistic and achievable.
- Set a date for re-audit (if appropriate).

Problem identified	Action	By Whom	By When
Re-audit:	Date:	By Whom:	

How has / will the clinical audit improve patient care? Please summarise the way in which your findings and implementation of recommendations will improve care.
References:
All full list of references should be provided using a recognised referencing system (such as Harvard).
Appendices:
Always include the clinical audit pro-forma within your appendices.
Ensure that a copy of the report is sent to the Clinical Effectiveness Department and the Specialty / Service clinical audit lead.