Reference Number: *UHB 510* **Version Number:** 1	**Date of Next Review:** *18.07.2026* **Previous Trust/LHB Reference Number:** *N/A*

Procedure for Review and Implementation of NICE, Health Technology Wales Guidance and All Wales Medicines Strategy Group

Introduction:

Rationale: The purpose of this document is to describe how guidance is disseminated and implemented across Cardiff and Vale University Health Board to provide assurance.

Principles: Cardiff and Vale UHB (University Health Board) is committed to implementing evidence-based practice to improve the quality of health and social care and reduce variation of care. Cardiff and Vales UHB will provide assurance to Welsh Government that national guidance has been reviewed, implemented and appropriately risk assessed and appropriately actioned. Where national guidance may not be considered as best practice, the UHB will provide evidence to Welsh Government that the guidance has been considered and the rationale for not implementing the guidance will be provided.

Policy Commitment

All guidance published by national guidance which include guidance issued by NICE, Health Technology Wales (HTW) and the All Wales Medicines Strategy group (AWMSG) will be reviewed, implemented and risk assessed.

NICE guidance covers:
NICE guidelines
TAG (Technology Appraisal Guidance)
Diagnostic guidance
Medical technology guidance
Interventional procedure guidance
Highly specialised technology guidance

HTW guidance covers:
Any non-medical technology and models of care

AWMSG covers:
The use, management and prescribing of medicines in Wales

All staff have a duty to be aware of all national guidance applicable to their speciality.

Supporting Procedures and Written Control Documents

- **Clinical Audit Policy**

Scope: This guidance is intended for all staff engaged with guidance review and implementation within the Cardiff and Vale UHB.

This includes all staff, clinician, management, senior management, and board members both clinical and non-clinical. Those with short term or honorary contracts, students, trainees in any discipline.
This guidance also applies to any work jointly undertaken across all professional boundaries. This document should also be read in conjunction with the Clinical Audit and Service Evaluation Policy.

Equality Impact Assessment	An Equality Impact Assessment (EqIA) Has been considered and not required.
Health Impact Assessment	A Health Impact Assessment (HIA) As above
Policy Approved by	QSE Committee
Group with authority to approve procedures written to explain how this policy will be implemented	Clinical Effectiveness Committee
Accountable Executive or Clinical Board Director	Executive Medical Director

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governanc Directorate.

Summary of reviews/amendments

Version Number	Date Review Approved	Date Published	Summary of Amendments
1	QSE approved on 18.07.2023	23.04.2024	*New Document*

Contents:

1 Introduction

National Institute for Health and Care Excellence (NICE)

The National Institute of Health and Care Excellence (NICE) (https://www.nice.org.uk) was established as a Special Health Authority in April 1999 and is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. In April 2013 NICE also gained responsibilities for providing guidance for those working in social care. NICE recommendations are based on independent reviews of evidence for clinical and cost effectiveness or interventions. Once NICE guidance is published health professionals, commissioners and organisations are expected to take the guidance fully into account when deciding what services, treatments, or advice to offer to service users and carers.

Implementing NICE guidance offers benefits to patients and carers, healthcare professional and organisations. A clear process for the management of NICE guidance helps ensure that care provided to patients is high quality and cost effective.

The treatment and care should consider individuals needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment in partnership with their healthcare professionals. The UHB is expected to take NICE recommendations fully into account to ensure a continuous review of services to provide the best outcomes of care. The process and systems in place for responding to best practice guidance published by NICE will help support the UHB in developing high quality services to ensure they're providing a safe and effective service.

Health Technology Wales (HTW)

Health Technology Wales (HTW) (https://healthtechnology.wales) is a national body working to improve the quality of care in Wales. HTW collaborate with partners across health, social care and the technology sectors to ensure an all-Wales approach.

HTW are an independent organisation which are funded by Welsh Government and hosted within NHS Wales. Their remit covers any technology or model of care and support in health and social care that isn't a medicine.

For health, this could include medical devices, diagnostics, procedures and psychological therapies. For social care, this could include equipment, or different models for supporting families, children, adults and the workforce. Workstreams consist of Identification, appraisals and adoption of health technologies.

The aim is to improve the quality of health and social care in Wales, by assessing the value and optimising the use of clinically and cost-effective technologies and models of care and support.

The process for identification, dissemination and implementation of HTW emulates the same process as for NICE guidance.

HTW also monitor the adoption of their guidance, and guidance from other organisations, across all of the local health boards in Wales and encourage adoption of guidance in social care. This not only includes uptake of new health and social care technologies, but also disinvestment in current technologies that are found to be less effective or obsolete.

All Wales Medicine Strategy Group (AWMSG)

The AWMSG advised Welsh Government about the use, management and prescribing of medicines in Wales. The role of AWMSG is to develop timely, independent and authoritative advice on new medicines. They advise Welsh Government about future developments in healthcare and help to develop a medicine prescribing strategy for Wales.

AWMSG will provide guidance for newly licensed and established medicines, they will conduct monitoring as part of its medicine optimisation programme. The optimisation programme aims to focus on patient and outcomes rather than process and systems and aims to support healthcare worker in advising patients on how they can achieve the best outcomes from their medicines.

AWMSG provide authoritative advice to Welsh Government and will assist with the implementation and audit of this advice within NHS wales. They will regularly analyse prescribing data in order to benchmark performance and drive improvements in the service.

1. Definitions

Best Practice - A best practice is a technique or methodology that, through experience and research, has proven to reliably lead to a desired result. A commitment to using the best practices in any field is a commitment to using all the knowledge and technology at one's disposal to ensure success.

Nice Guidance – NICE Guidance covers the following classifications

NICE currently develop and publish the following types of guidance

- NICE guidance
- Technology appraisal guidance
- Diagnostic guidance
- Medical technology guidance
- Interventional procedures guidance
- Highly specialised technology guidance

NICE guidelines	Cancer services guidelines	The focus is to guide the commissioning of services and is therefore different from clinical practice guidelines. Based upon the implementation of the NHS Cancer Plan
	Clinical guidelines	Provide guidelines on the appropriate treatment and care of patients with specific disease and conditions.
	Medicines practice guidelines	Provide recommendation for good practice for those individuals and organisations involved in governing, commissioning, prescribing and decision making about medicines. they have a wide range of audiences across both health and social boards.
	Public health guidelines	Make recommendations for populations and individuals on activities, policies and strategies that can help prevent disease or improve health.
	Social care guidelines	Aim to provide outcomes for people who use social care support by ensuring that social care services and interventions are effective and cost efficient.
Technology Appraisal guidance		Technology Appraisals provide guidance on the use of new and existing medicines, treatments and procedures within the National Health Service (NHS) These follow a slightly different process for assessment and implementation within the Trust to the other NICE Guidance listed above and therefore at the end of each subsection in section 6 a separate italicised statement has been made in relation to TAs.
Diagnostic guidance		Focus on the evaluation of innovative medical diagnostic technologies in order to ensure that the NHS can adopt clinically and cost-effective technologies more rapidly and consistently.
Medical technologies guidance		Focus specifically on the evaluation of innovative medical technologies (including devices and diagnostics).
Interventional procedures guidance		These recommend whether interventional procedures - such as laser treatments for eye problems or deep brain stimulation for Implementation of NICE Guidance Policy April 2020 Version 5 Page 3 of 17 chronic pain - are effective and safe enough for use in the NHS.
Highly specialised technologies guidance		Contain recommendations on the use of highly specialised technologies.

2. Duties and Responsibilities:

Medical Director: Is the Executive Lead with the overall strategic responsibility to ensure the system is in place to monitor compliance, ensuring all national guidance and quality standards published by NICE, HTW and AWMSG are implemented across the UHB, escalating any risks to the board

Identified guidance leads: Identified leads can be Clinical Directors, Heads of Specialities or anyone appointed by Clinical Directors to complete the baseline assessment, oversee, and implement any action plans.

Clinical Directors: The Clinical Directors are accountable for reviewing all guidance published by NICE, HTW and AWMSG and determining their relevance to the UHB or their clinical area. They are accountable for ensuring that a lead is appointed for all guidance that has been identified as relevant for their clinical speciality. They must ensure baseline assessments are completed and action plans are implemented.
The Clinical Directors also have the responsibility for ensuring that guidance is shared within their clinical area and discussed at Directorate Quality and Safety and appropriate governance meetings. They must ensure that they inform the Quality Assurance Team of any risks to the UHB when they are identified. They will ensure that the risk register is updated where non-compliance poses patients at risk.

Clinical Audit and Quality Assurance Lead: The Clinical Audit and Quality Assurance Leads are responsible for the coordination and distribution of new guidance/quality standards to Clinical Directors or designated clinical leads and will maintain the guidance database and they will provide support and advise to relevant staff. They will also provide reports to the Medical Director on an agreed basis.

The Head of Patient Safety and Quality Assurance/Deputy Head of Quality Assurance and Clinical Effectiveness Lead: Have overall responsibility to ensure compliance is monitored and reported to internal and external stakeholders. They are responsible for ensuring that the UHB compliance with all national guidance is monitored at the relevant Quality and Safety Meetings and raising any concerns to the Medical Director.

Clinical Effectiveness Committee: The committee will be the group responsible for overseeing this process and will receive assurance reports as per the reporting schedule.

Healthcare Professionals Groups: All healthcare professionals employed by Cardiff and Vale University Health Board are responsible for ensuring that they understand the significance, relevance, and impact on their daily practice of national guidance.

Other professional groups: All guidance and relevant quality standards must be brought to the relevant quality and safety groups/meetings where it can be discussed and disseminated including guidance for information only.

3. Procedure:

Identifying new guidance

NICE, HTW and AWMSG publish new and updated guidance which are available via their websites https://www.nice.org.uk , https://healthtechnology.wales , https://awttc.nhs.wales. New and revised guidance will also be added to the AMaT data base. The Clinical Audit / Quality Assurance Team will review and identify new and revised guidance by its published date and will disseminate the guidance via AMaT to the relevant Clinical Director / Clinical Team and request feedback of the guidance relevance to the UHB.

The Clinal Audit / Quality Assurance Team will require evidence of compliance of all guidance that has been adopted into the UHB. All new and revised NICE guidance will include a 'baseline assessment tool' which can be accessed via the NICE website (https://www.nice.org.uk).
The assessment is intended to identify whether there is currently sufficient evidence available for each recommendation within the guidance including whether the guidance is being followed and/or standards are being met. All guidance will require evidence of compliance and this evidence may come in different forms and consideration should be given to:

- Relevant policies and procedure may identify whether a guidance recommendation is already incorporated into the UHB expectations
- Electronic systems may hold various information which supports the assessment of whether the recommendation is being followed.
- The Clinical Audit Team will be able to provide previous audit data (if previous audit has been correctly registered with the UHB) which may be of use.
- Where information is not available this should be flagged within the relevant assessment tool.

Any evidence used to support completion of the assessment should be identified within the relevant assessment tool. It should also be clearly identified where data is not currently captured and where data is needed to determine compliance and any future data that will be required. (for inclusion in the action plan). All evidence will need to be uploaded onto AMaT.

It is expected that assessments will be completed on AMaT within 30 days. The Clinical Director / Clinical lead will therefore need to ensure the assessment has been presented to relevant groups for approval prior to being uploaded onto AMaT which will in turn notify the Clinical Audit / Quality Assurance Team.

4. Evidence to Support Assessment

NICE provide an assessment tool which can either be accessed via AMaT or their website (https://www.nice.org.uk). An assessment tool can be completed as either as an initial assessment or a re-assessment), the Clinical Director /Clinical Lead is expected to describe what evidence they have and must substantiate a status of compliance with each recommendation in the guidance.

Evidence to support compliance may include clinical audit results, patient surveys, policies, reports, data generated from an electronic system, service leaflets and / or other documentation.

Where evidence is not currently available, steps to obtain evidence should be included in an action plan

5. Statement of Compliance

For all guidance, a statement of compliance will be required which will be completed via the AMaT system (AMaT Guidance Module). The compliance review tool will include a text box for each recommendation to allow comments for any identification of risks where there is currently insufficient evidence of current. The Clinical Board will scrutinise the completed statement of compliance review and will be expected to consider the overall risk to quality of care where full compliance is not declared.

Determination of risk should consider:

- How many recommendations do not have sufficient evidence of compliance
- The significance of these recommendations
- Whether it is believed that the UHB is compliant but there is a lack of evidence available at this time, or whether it is believed that the UHB is not compliant
- The amount of work required to implement the recommendation
- What actions can be taken to mitigate against any risks

6. Approval of Statement Reviews

All completed statements will be submitted onto AMaT (Guidance Module). The Quality Assurance/Clinical effectiveness team will review, approve or request additional information if necessary for each assessment.

Where the compliance statement indicate that there are recommendations to which the health board is not compliant, or there is insufficient evidence of compliance, the Quality Assurance/Clinical effectiveness team will ask the clinical lead to attend the Clinical Effectiveness Committee to discuss the level of risk posed by non-compliance and consider inclusion of these risk/s within the relevant risk registers and describe the actions taken to mitigate against the risks

7. Action Plan

Once the completed statements of compliance have been submitted onto AMaT, the assessor or clinical lead will be responsible for generating an action plan to bring the health board into a position where it is compliant with the NICE, HTW and/or AWMSG guidance and/or is able to generate sufficient information to demonstrate compliance.

Common elements on an action plan may include:

- Undertake further assessment
- Amendments to relevant policies/procedures, including ongoing monitoring requirements (to provide ongoing evidence of compliance)
- Training of staff
- Communication to staff of changes to policy
- Audit (Local/isolated or inclusion on clinical audit plan)
- Re-assessment (this should be included on all action plans as re-assessment will need to occur once other actions are implemented.

In generating an action plan the clinical lead should identify whether they believe additional resources will be required to complete the action, which action these effects, and the extent to which the identified risk can be mitigated without additional resources being made available. These considerations should be submitted to the Quality Assurance/Clinical Effectiveness team at the same time as the action plan.

The action plan should be uploaded onto AMaT within one month of the statement of compliance has been completed. The Quality Assurance/Clinical Effectiveness team will approve the action plan and may request amendments and resubmissions for approval. Prior to uploading any/all documents/evidence/action plans it is expected that the Clinical Board Leads have reviewed and approved each document.

By approving each action plan, the Quality Assurance/Clinical Effectiveness team will ensure implementation of multiple guidance recommendations is co-ordinated and prioritised across the health board.

Common elements will be brought together and actioned 'en-masse' e.g. if 3 action plans contain amendments to insight then these will be brought together and 1 request for amendments made to the relevant technical team.

Clinical Audit requirements should be taken from the action plan and co-ordinated by the clinical audit leads/Governance leads within the directorate. These should be incorporated onto AMaT in an efficient and effective manner and may be included as part of the Annual Clinical Audit Forward Plan

8. Ongoing Evidence of Compliance

Clinical and Professional Directors are responsible for ensuing guidance and other best practice guidance are implemented as much as possible across the organisation. All staff providing care and treatment have the responsibility to provide care that is safe and effective and therefore compliance with best practice guidance is expected. When reviewing existing policies and procedures, or writing new ones, policy authors are responsible for ensuring that relevant guidance published by NICE, HTW and AWMSG and their recommendations are incorporated and that these documents describe a 'NICE, HTW or AWMSG COMPLIANT' service.

The Quality Assurance/Clinical Effectiveness will monitor ongoing evidence of compliance. As well as reassessments of guidance and implementation of the health boards policies, ongoing evidence may also include 'additional evidence' which will include other activities/developments within the health board that address recommendations and standards contained within the NICE, HTW and AWMSG guidance.

Ongoing evidence of compliance will in part be linked to policy monitoring and will be the responsibility of the group that is identified in the policy as having those responsibilities.

10. Decision not to Implement Recommendations

Where there are insufficient resources available to implement recommendations contained within NICE, HTW and AWMSG guidance, and a business case to secure funds has been unsuccessful, it will be expected that the clinical lead will notify the Clinical Effectiveness Committee.

Arrangements should be made to add a risk assessment to the risk register if one has not already been done. The Clinical Effectiveness Committee will expect the relevant clinical teams to implement a plan to mitigate against any risks, these plans should be presented to the Clinical Effectiveness Committee and escalated to the QSE as Exception.

11. Annual Review of Recommendation/s not Previously Implemented

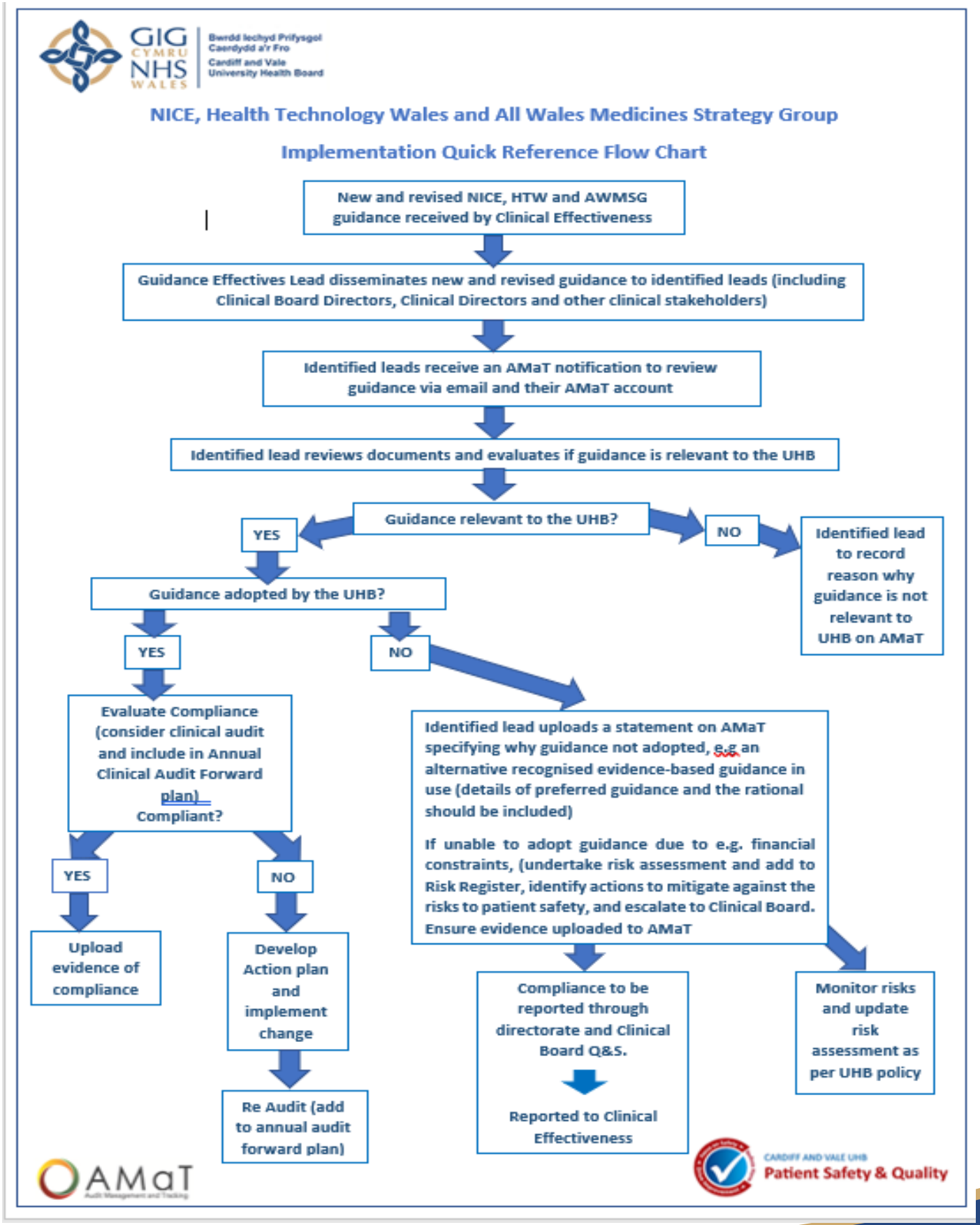
The time interval for the review of NICE, HTW and AWMSG guidance not implemented should be determined on the level of risk identified. Where reports have identified individuals/groups who have not complied with the processes and timeframes outlined in this policy the Assistant Medical Director will contact the individual/chair of the group. The Assistant Medical Director will request an explanation and agree a method of restabilising the process as soon as possible.

12. Reporting

The Quality Assurance/Clinical effectiveness Team will maintain a NICE, HTW and AWMSG compliance data on AMaT, this will include all the information necessary for monitoring the application of this policy.

The following should be submitted for guidance on AMaT

- All completed relevant assessment and accompanying risk assessment, in relation to NICE guidance.
- Action plans for approval
- A report outlining guidance where it has been decided not to implement recommendations, for approval
- A list of newly published guidance, identifying relevance to guidance


GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board
NICE, Health Technology Wales and All Wales Medicines Strategy Group
Implementation Quick Reference Flow Chart
New and revised NICE, HTW and AWMSG guidance received by Clinical Effectiveness
Guidance Effectives Lead disseminates new and revised guidance to identified leads (including Clinical Board Directors, Clinical Directors and other clinical stakeholders)
Identified leads receive an AMaT notification to review guidance via email and their AMaT account
Identified lead reviews documents and evaluates if guidance is relevant to the UHB
Guidance relevant to the UHB?
YES
NO
Identified lead to record reason why guidance is not relevant to UHB on AMaT
Guidance adopted by the UHB?
YES
NO
Evaluate Compliance (consider clinical audit and include in Annual Clinical Audit Forward plan)
Compliant?
YES
NO
Upload evidence of compliance
Develop Action plan and implement change
Re Audit (add to annual audit forward plan)
Identified lead uploads a statement on AMaT specifying why guidance not adopted, e.g an alternative recognised evidence-based guidance in use (details of preferred guidance and the rational should be included)
If unable to adopt guidance due to e.g. financial constraints, (undertake risk assessment and add to Risk Register, identify actions to mitigate against the risks to patient safety, and escalate to Clinical Board. Ensure evidence uploaded to AMaT
Compliance to be reported through directorate and Clinical Board Q&S.
Reported to Clinical Effectiveness
Monitor risks and update risk assessment as per UHB policy
AMaT
CARDIFF AND VALE UHB
Patient Safety & Quality