NICE Guidelines
Final Internal Audit Report
September 2023

Hywel Dda University Health Board

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Gwasanaethau Archwilio a Sicrwydd
Shared Services Partnership
Audit and Assurance Services

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

Contents

Review reference:	HDUHB-2324-14
Report status:	Final
Fieldwork commencement:	26 May 2023
Fieldwork completion:	13 July 2023
Debrief meeting:	19 July 2023
Draft report issued:	19 July 2023
Management response received:	23 August 2023
Executive sign-off:	4 September 2023
Final report issued:	4 September 2023
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Committee:	Audit & Risk Assurance Committee

Audit and Assurance Services conform with all Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Chartered Institute of Public Finance & Accountancy in April 2023.

Acknowledgement:
NHS Wales Audit and Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

Executive Summary

Purpose

The purpose of the audit is to review the arrangements in place for ensuring identification, dissemination and compliance with NICE guidelines across the Health Board.

Overview

The arrangements for disseminating and ensuring compliance with NICE guidelines have evolved with the implementation of the Audit Management & Tracking (AMaT) system in 2022, which will take time to fully embed and deliver real benefit.

The Clinical Effectiveness Team encourages engagement from clinical/service areas and provides support, where capacity allows, with the completion of compliance assessments and attendance at quality and safety forums to raise awareness of NICE guidelines. Notwithstanding this, at the time of our review a significant number of guidelines did not have leads assigned to complete statements of compliance and therefore compliance assessments have not been completed.

Whilst there is a governance structure in place for monitoring and reporting, at present there is no oversight of NICE guideline compliance or progress in assessing this across the Health Board.

We have concluded **Limited** assurance overall – this specifically relates to the operation of arrangements in place for assessing and ensuring compliance with NICE guidelines, and is not a reflection of the extent to which the Health Board is compliant with these guidelines.

Key matters arising are summarised below with full details provided in Appendix A.

Report Opinion

		Trend
Limited 	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved.	N/A

Assurance summary[1]

Objectives		Assurance
1	New or updated NICE guidelines is identified and disseminated through the Health Board	Reasonable
2	Implementation of NICE guidelines is monitored	Limited
3	Mechanisms exist to provide assurance on compliance with NICE guidelines	Limited

[1]The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.

Key Matters Arising

		Objective	Control Design or Operation	Recommendation Priority
1	Guidance Dissemination	1	Operation	Medium
2	Nominated Leads	2	Operation	High
3	Compliance Monitoring & Assurance Reporting	3	Design	Medium High

1. Introduction

1.1 Evidence-based national guidance and standards should be followed by all health professionals in order to provide high standards of health and social care to patients within Hywel Dda University Health Board (HDUHB) and implementation of agreed guidelines ensures the most effective use of Health Board resources.

1.2 National Institute for Health and Care Excellence (NICE) guidelines are evidence-based recommendations developed by independent committees, including professionals and lay members and consulted by stakeholders and have been produced by NICE in order to improve outcomes for people using the NHS and other public health and social care services.

1.3 Whilst the application of NICE recommendations is not mandatory in Wales, the Welsh Government is working with NICE to improve quality in health and social care in Wales and in accordance with this Hywel Dda University Health Board is required to:

- develop systems and processes for disseminating, implementing and risk assessing against NICE guidelines and quality standards
- identify any gaps and action required to improve the quality of services
- provide assurance to Welsh Government that NICE guidelines have been considered, if requested

1.4 The associated potential risks are:

- poor quality services provided to patients, resulting in patient harm and/or negative patient experience
- reputational damage to the Health Board; and
- financial loss to the Health Board

1.5 The review sought to establish and assess the appropriateness of mechanisms in place to disseminate and ensure compliance with NICE guidelines, but not to confirm the extent to which NICE guidelines are complied with. The review focused on NICE guidelines (also known as clinical guidelines).

2. Detailed Audit Findings

Objective 1: Processes are in place to ensure that new or updated NICE guidelines are identified and disseminated throughout the Health Board

2.1 Health Board Policy *013 Management of NICE and other National Guidance* sets out the arrangements for implementing, monitoring and reporting progress in relation to NICE guidance and Quality Standards. This is supported by *Flow Chart 013 NICE and National Guidance Policy*. Both documents are up to date and accessible to staff via the intranet.

2.2 In 2022 the Health Board implemented the Audit Management and Tracking (AMaT) system to facilitate the identification and dissemination of NICE and other national guidelines. New and updated NICE guidelines are automatically published to AMaT by NICE, the Clinical Effectiveness Team then disseminate the guidelines to the service triumvirate through AMaT within a full audit trail maintained by the system.

2.3 We identified 53 NICE guidelines published in AMaT during the period March 2022 – June 2023. Sample testing of 12 guidelines confirmed there was evidence within AMaT to demonstrate dissemination in all but one case relating to a guideline issued in October 2022. Whilst policy does not stipulate a timescale for disseminating NICE guidelines following publication in AMaT, the sample of 12 guidelines reviewed took an average of 28 days, but in four cases over to 30 days, to be disseminated. **[Matter Arising 1]**

2.4 The Clinical Effectiveness team raise awareness of newly published guidelines at the directorate Quality, Safety & Assurance Groups, the Clinical Standards & Guidelines Group, via the quarterly NICE and National Guidance Bulletin distributed through global emails and add links to new guidance on the staff intranet. We confirmed that a summary of each of the guidelines in our sample had been presented at a sample of twelve Quality, Safety & Assurance Group meetings.

2.5 NICE guidance scope publications are communicated via quarterly bulletins and sent to relevant service leads to encourage them to sign up as a stakeholder, so they have an opportunity to comment on developing guidelines out for consultation. This process is supported by the Clinical Effectiveness Team and demonstrated with examples.

Conclusion:

2.6 The process of identifying and disseminating NICE guidelines is more robust and efficient with the implementation of the AMaT system. Sample testing identified one instance where new/updated guidelines had not been disseminated, and there is opportunity to improve the timeliness of dissemination. Accordingly, we have concluded **Reasonable** assurance for this objective.

Objective 2: Systems are in place to monitor the implementation of NICE guidance, with actions to achieve compliance identified and progressed

2.7 The Health Board has a responsibility to promote application and adherence to guidance where applicable and the Clinical Effectiveness team is responsible for gaining assurance from services that guidance has been implemented. AMaT provides a mechanism to capture assessments against NICE guidelines, identify risks and barriers to compliance, and develop actions plans to achieve compliance.

Nominated Leads

2.8 Policy states that nominated clinical and service leads must acknowledge and maintain ownership for allocated guidelines and are responsible for:

- ensuring completion of compliance reviews within AMaT
- considering whether a full baseline assessment is required
- ensuring completed baseline assessments are uploaded on AMaT and discussed at appropriate directorate quality governance groups
- effective risk management where gaps or barriers to compliance have been identified, escalating where appropriate

2.9 NICE guidance is issued to the service triumvirate requesting identification of a nominated clinical or service lead to manage completion of compliance statements within the AMaT system. Nominated leads had been identified by the overall clinical or service lead for only 11 of the 53 guidelines published between March 2022 – June 2023. **[Matter Arising 2]**

2.10 We sampled 10 guidelines without nominated leads and confirmed that a request to identify a lead had been issued with the guidelines, but no response received and there was no follow up by the Clinical Effectiveness Team. **[Matter Arising 2]**

2.11 We contacted 10 clinicians who had received an email notification of new/updated guidance, to gauge their perspective, understanding of and engagement in the process. Four clinicians responded, with two recalling receipt of a notification of new/updated NICE guidelines although they had not taken any action.

2.12 Three respondents stated that they had not received training on the AMaT system, with two having since liaised with the Clinical Effectiveness Team to arrange this. Training videos, guides and tutorials are available on SharePoint and within AMaT, and there are prompts within the system to support ease of use. Training is provided by the Clinical Effectiveness Team on request, and the team cited examples of system demonstrations to raise awareness of AMaT across the Health Board.

Statements of Compliance

2.13 Policy states that assessment of the guideline compliance status should be completed within six weeks, although it is not clear whether this commences when the guidance is issued by NICE, disseminated by the Clinical Effectiveness Team, or identification of a lead. The statement of compliance had been completed for one of the 11 guidelines with a nominated lead, with a further six in progress (not

yet due) and four showing as overdue by up to seven months. **[Matter Arising 2 & 3]**

2.14 The Clinical Effectiveness Team cited examples of where they are supporting service areas to review compliance against NICE guidelines using AMaT and identify areas for improvement, culminating in two service areas attending the CSGG to present their work.

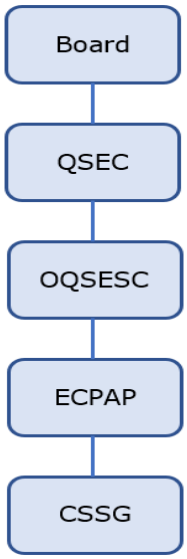
2.15 Baseline assessments can be used as an optional tool to further explore any gaps in compliance identified in the statement of compliance reviews, and support development of actions to address these gaps. Noting the position with statement of compliance reviews, it follows that no assessments have been completed or actions identified for NICE guidelines published during the period reviewed.

Conclusion:

2.16 The AMaT system offers an efficient and effective mechanism for documenting and evidencing NICE guideline compliance, although its value is entirely dependent on the engagement of clinical/service leads. Whilst the Clinical Effectiveness Team are disseminating guidelines, most guidelines issued since March 2022 do not have a lead assigned by the overall Clinical/Service lead to complete a statement of compliance and therefore compliance has not been assessed. We recognise the relative infancy of the AMaT system, but this simply replaces a previously manual process - the requirement to assess NICE guideline compliance is not new. Accordingly, we have concluded **Limited** assurance for this objective.

Objective 3: Mechanisms exist to provide assurance on compliance with NICE guidance, with regular monitoring and reporting through the Health Board's Quality & Governance structures

2.25 Monitoring and reporting arrangements are set out within the *Management of NICE and Other National Guidance Policy* and supporting flow chart.



2.26 The CSGG is responsible for providing assurance to the *Effective Clinical Practice Advisory Panel (ECPAP)* that assessments of NICE guidelines are taking place, and that the Health Board is meeting the expectations set out within these guidelines.

2.27 CSGG minutes demonstrate reporting of new/updated NICE guidelines including some examples highlighting overall compliance with specific guidelines, and there is evidence of regular reporting to the ECPAP. However, the group does not receive sufficient information to have oversight of, and therefore provide assurance to ECPAP (and ultimately the Board) in relation to progress with compliance assessments, the compliance status of all NICE guidelines and actions to improve this. **[Matter Arising 3]**

2.28 The *Operational Quality, Safety and Experience Sub Committee (OQSEC)* is responsible for ensuring and monitoring compliance with national guidance including NICE guidelines, although we note that ECPAP does not routinely report to OQSEC, but may escalate exceptional matters where appropriate. ECPAP does however report six-monthly to the *Quality, Safety & Experience Committee (QSEC)* to provide an overview of the wider clinical effectiveness agenda and a summary of key matters discussed by the panel.

Conclusion:

2.29 Whilst there is evidence of discussion and reporting relating to NICE guidelines at the CSGG, ECPAP and QSEC, there is no oversight or assurance reporting at any level from CSGG to the Board, in relation to progress with compliance assessments and the compliance status of all NICE guidelines. The role of OQSESC and QSEC in the governance arrangements is also unclear as reporting is not consistent with terms of reference. We have therefore concluded **Limited** assurance for this objective.

Appendix A: Management Action Plan

Matter Arising 1: Guidance Dissemination (Operation)			**Impact**
We identified 53 NICE guidelines published in AMaT during the period March 2022 – June 2023. Sample testing of 12 guidelines confirmed there was evidence within AMaT to demonstrate dissemination in all but one case relating to a guideline issued in October 2022. Whilst policy does not stipulate a timescale for disseminating NICE guidelines following publication in AMaT, the sample of 12 guidelines reviewed took an average of 28 days, but in four cases over 30 days, to be disseminated.			Potential risk of: • Poor or ineffective clinical practice due to non-compliance with NICE guidelines, potentially resulting in detrimental impact on patient safety and/or experience
Recommendations			**Priority**
1.1	Determine an appropriate timescale for the dissemination of NICE guidelines following publication within AMaT.		**Medium**
Agreed Management Action		**Target Date**	**Responsible Officer**
1.1	A new process has been introduced from the 1st August 2023 to disseminate newly published and updated NICE guidance weekly upon receipt of the AMaT Roundup every Monday.	1st August 2023 (complete)	Donna Edwards, Clinical Effectiveness Officer

Matter Arising 2: Nominated Leads (Operation)			**Impact**
Nominated leads to complete the statement of compliance had been identified by the overall clinical or service lead for only 11 of the 53 guidelines published between March 2022 – June 2023. We sampled 10 guidelines without nominated leads and confirmed that a request to identify a lead had been issued with the guidelines, but no response received.			Potential risk of: • Poor or ineffective clinical practice due to non-compliance with NICE guidelines, potentially resulting in detrimental impact on patient safety and/or experience
Recommendations			**Priority**
2.1a	Identify appropriate/nominated contact(s) for each clinical/service area for the Clinical Effectiveness Team to disseminate new/updated NICE guidelines to, and with responsibility for identifying and nominating a lead for each guideline.		**High**
2.1b	When disseminating guidelines, the Clinical Effectiveness Team should stipulate a deadline for identifying a nominated lead. Guidelines without a nominated lead should be monitored and followed up by the Clinical Effectiveness Team, with regular reporting of those outstanding to the CSGG.		
Agreed Management Action		**Target Date**	**Responsible Officer**

2.1a	A new approach has been introduced to disseminate new and updated NICE guidance directly to the Service Lead within AMaT, identified by the Clinical Effectiveness Team, with the ability of the Service Lead to reallocate within AMaT. The Clinical Effectiveness Team will become Guideline Lead in order to maintain oversight and support collation of Health Board statement of compliance. To allocate the Directorate Quality and Governance Lead as Stakeholder for all relevant guidelines.	1st August 2023 (complete) 31st December 2023 (dependent on meeting dates to present the SBAR)	Donna Edwards, Clinical Effectiveness Officer
2.1b	Recommendation not applicable as process has changed as per response to 2.1a	n/a	n/a

Matter Arising 3: Compliance Monitoring & Assurance Reporting (Design / Operation)	**Impact**
The CSGG does not receive sufficient information to have oversight of, and therefore provide assurance to ECPAP (and ultimately the Board) in relation to progress with compliance assessments, the compliance status of all NICE guidelines and actions to improve this. According to terms of reference, OQSEC is responsible for ensuring and monitoring compliance with national guidance including NICE guidelines. However, ECPAP does not routinely report to OQSEC. ECPAP does however report six-monthly to the *Quality, Safety & Experience Committee (QSEC)* to provide an overview of the wider clinical effectiveness agenda and a summary of key matters discussed by the panel.	Potential risk of: • Poor or ineffective clinical practice due to non-compliance with NICE guidelines, potentially resulting in detrimental impact on patient safety and/or experience

Recommendations		Priority
3.1	Review the governance reporting arrangements, including the role of the OQSESC, to ensure they are efficient and fit for purpose.	**Medium**
3.2	In order to fulfil its responsibilities per the terms of reference and facilitate assurance reporting to ECPAP (and ultimately the Board), the CSGG should receive regular reporting on the number of new/updated NICE guidelines: - published by NICE and included in AMaT - disseminated to clinical/service leads - awaiting identification of a nominated lead to complete the statement of compliance - where compliance statements are not started/in progress/overdue/complete When there is sufficient progress with compliance assessments and therefore data available within AMaT, this reporting should be extended to include the compliance status of each guideline, the completion of baseline assessments and action plans to achieve/improve compliance.	**High**

Agreed Management Action		Target Date	Responsible Officer
3.1	To conclude the current review of governance arrangements, discussing the role of the ECPAP, OQSESC and QSEC, alongside the Directorate Quality and Governance Groups; and amend the Terms of Reference accordingly. To develop an SBAR outlining the new reporting arrangements and recommending adoption. To present the SBAR outlining the new reporting arrangements to the following: - Directorate Quality and Governance Groups (dependent on scheduled dates)	4th September (complete) 4th September 2023 (complete) By 31st December 2023 (dependent	Lisa Davies, Head of Effective Clinical Practice and Quality Improvement

	- OQESC (8th November 2023) - ECPAP (5th September 2023) - CSGG (7th November 2023)	on meeting dates to present the SBAR)	
3.2	From 1st August the following reports will be generated from AMaT and provided to CSGG and ECPAP at every meeting: - published by NICE and included in AMaT - disseminated to clinical/service leads - where compliance statements are not started/in progress/overdue/complete (Reporting on New/Updated NICE guidelines awaiting identification of a nominated lead to complete the statement of compliance will no longer be applicable due to the change in process per response to matter arising 2.1a).	1st August 2023 (complete)	Donna Edwards, Clinical Effectiveness Co-ordinator

Appendix B: Assurance opinion and action plan risk rating

Audit Assurance Ratings

We define the following levels of assurance that governance, risk management and internal control within the area under review are suitable designed and applied effectively:

	**Substantial assurance**	Few matters require attention and are compliance or advisory in nature. **Low impact** on residual risk exposure.
	**Reasonable assurance**	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.
	**Limited assurance**	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved.
	**Unsatisfactory assurance**	Action is required to address the whole control framework in this area. **High impact** on residual risk exposure until resolved.
	**Assurance not applicable**	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

Prioritisation of Recommendations

We categorise our recommendations according to their level of priority as follows:

Priority level	Explanation	Management action
High	Poor system design OR widespread non-compliance. Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in system design OR limited non-compliance. Some risk to achievement of a system objective.	Within one month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. Generally issues of good practice for management consideration.	Within three months*

* Unless a more appropriate timescale is identified/agreed at the assignment.

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