Review and Implementation of NICE Guidance, National Guidance and National Confidential Enquiries Procedure

Appendices

Appendix	Details
Appendix 1	The Identification and Implementation process for NICE guidance and National Guidance publications
Appendix 2	NICE TAG Proforma details the information required for submission to the Governance Officer **and** includes TAG process
Appendix 3	NICE TAG Implementation of NICE Approved Drugs
Appendix 4	NICE Proforma All guidance excluding TAGs details the information required for submission to Governance
Appendix 5	Gap analysis / action plan template
Appendix 6	The monitoring process following request for closure of National Guidance

1.0 Procedure Statement

The purpose of this procedure is to ensure that there are robust processes in place for the review and implementation of best practice of new and existing NICE and National Guidance to satisfy the following requirements.

- The Trust database is kept up to date and monitored appropriately.
- The Trust can provide assurance to commissioners of due process.
- There will be a standardised approach to the review, implementation, and compliance of NICE and National Guidance and recommendations.

Royal College reports and speciality specific guidance are managed through local governance processes any escalation of concerns will go through Directorate/Division to Trust level group if required.

2.0 Definitions

2.1 National Institute for Health and Care Excellence (NICE) guidance.

NICE guidelines are evidence-based recommendations for health and care in England. They set out the care and services suitable for most people with a specific condition or need, and for people in particular circumstances or settings. NICE guidelines help health and social care professionals to prevent ill health.

2.2 National Guidance and National Confidential Enquiry (NCEPOD)

NCEPOD's purpose is to assist in maintaining and improving standards of care for adults and children for the benefit of the public by reviewing the management of patients, by undertaking confidential surveys and research, by maintaining and improving the quality of patient care and by publishing and generally making available the results of such activities.

3.0 Accountabilities

3.1 Trust Board

The Trust Board is responsible for ensuring that the Trust complies with relevant national best practice and mandatory standards published as National Guidance.

3.2 The Chief Executive (CEO)

The CEO is responsible for ensuring that National Guidance and NCEPOD recommendations are effectively and efficiently managed.

3.3 Executive Directors

For public level enquiries and guidance with a Trust-wide remit, the allocation of a lead will be completed by a member of the Executive Director Team.

3.4 NCEPOD Local Reporter (NCEPOD LR)

The NCEPOD LR is the Trust lead responsible for providing a link between the Confidential Enquiry body and the Trust and has the following responsibilities.

- Disseminating the reports from National Confidential Enquiries to key stakeholders within the Trust.
- Dissemination of the NCEPOD newsletter to give advanced notice of future planned studies to key stakeholders.
- Collecting data and collating a Trust Response.

3.5 Divisional Medical Directors are responsible for assessing the relevance of guidance (NICE and National Guidance) to the Trust and ensuring that there is an appropriate nominated lead for all guidance identified as applicable.

3.6 The Divisional Management Team is responsible for the scrutiny and challenge of assurance given for each piece of guidance (NICE and National Guidance) at Divisional level. They are also responsible for monitoring the completion of the Implementation of NICE Approved Drugs form within timescales in relation to any NICE Technology Appraisal Guidance (TAG) adopted by the Trust.

3.7 The Directorate Management Team (Clinical Director/Directorate Manager/Group Manager)

For NICE Guidance (NG) and Clinical Guidelines (CG) a baseline assessment tool produced by NICE is to be completed by the nominated lead and held locally.

Minutes from directorate and divisional governance and related relevant meetings must show detail of gaps identified and monitoring actions to completion. Directorates are accountable to produce any evidence and assurance of guidance status as required.

Directorates to present NICE guidance that hit a barrier initially to Divisional

Management Team and then NICE Implementation Group.

3.8 Trust Directorate Management Team

3.9 Trust NICE Implementation Lead

The Trust NICE Implementation Lead is responsible for the review of the internal NICE register and for receiving information from other responsible groups on the implications. She or he is also responsible for providing a report and an exception report to the Quality and Safety Advisory Group and for ensuring guidance is implemented as fully as possible. Appropriate NICE guidance will be o be allocated to Annual Clinical Audit Plans.

3.10 **The Nominated Lead** is responsible for reviewing the NICE/National Guidance and submitting a response within timescales and for providing timely updates for monitoring to completion. The initial response to Governance must identify any gaps, rationale or assurance of planned actions required either on the NICE proforma, in an email or an action plan/gap analysis.

3.11 **The Compliance Officer** will be alerted to or will or search websites for new NICE and National guidance publications and must disseminate the National guidance report, NICE guidance, and relevant documents to nominated leads and coordinate a response.

3.12 **Governance Team Leaders** are responsible for overseeing implementation processes at directorate level and for providing timely compliance and exception reports to Division (via the Healthcare Governance Managers). They must ensure that appropriate guidance is proposed for inclusion on directorate Clinical Audit Plans.

3.13 **Directorate Governance Officers** are responsible for supporting the nominated Lead with completion of relevant paperwork. They must provide exception reports for review at the appropriate directorate governance meetings. They must keep the Trust central database system updated with information regarding implementation and audit status.

3.14 **NICE Implementation Group** is chaired by the Trust NICE Implementation Lead and provides assurance on NICE guidance to Quality and Safety Advisory Group

3.15 **Quality and Safety Advisory Group (QSAG)** is responsible for the monitoring and review of NICE and National Guidance implementation, providing assurance to the Quality Governance Assurance Committee (QGAC).

3.16 **The Clinical Audit Group (CAG)** is accountable for ensuring all implemented NICE guidance identified for audit on a risk-based approach is audited within the appropriate timeframe.

4.0 Procedure Detail / Actions

This procedure refers to central monitoring of all National Guidance which may be issued from various sources such as NCEPOD reports or from the Department of Health.

It is to be noted that Royal College reports and specialty specific guidance are excluded from central monitoring; they are managed through local governance processes.

Directorates will escalate any local guidance that may require review by Divisional Management Team, and, if required, the Divisional Management Team will escalate to Quality and Safety Advisory Group

4.1 Implementing guidance NOT supported/recommended by NICE

Clinicians must present a paper to Quality and Safety Advisory Group that details:

- The proposed procedure.
- How they will ensure that patients understand the risks/uncertainty about the procedure's safety and efficacy.
- What clear written information and counselling support both before and after the procedure will be offered to the patient.
- How audit and review of the clinical outcomes of all patients undergoing NICE non approved procedures will be completed.
- Risk assessment scoring (as per OP10).

Timeframes for Implementation of Guidance

Timeframes according to date issued to Lead and date of implementation	**Action required**
1 month (initial response) – NICE TAGs only	Return TAG NICE proforma or email response to governance officers identifying status
3 months (Full Implementation) – NICE TAGs only	Mandatory Implementation for NICE TAGs
2 month– all other NICE guidance	Response to Governance Officers identifying any gaps/rationale status providing assurance of planned actions required either on the NICE proforma, in an email or an action plan/gap analysis. It is to be noted: QS are evidence-based statements to deliver quality improvements which are based on previously published Clinical Guidelines (CG). These are seen as gold standard and monitored by the Trust in line with all other guidance as a measure of good practice.

3 months response National Guidance	Complete and submit a gap analysis/action plan identifying any gaps/rationale of status providing assurance of planned actions required to Compliance Officers, Governance for presentation to Divisional Governance and Quality and Safety Advisory Group.

4.2 Non implementation recommended by NICE

Where the nominated lead feels that the NICE guidance cannot be implemented, the NICE proforma must be completed identifying the reasons for non-implementation. An exception report giving a clear rationale must be submitted to Divisional Management Team and assurance provided to the NICE Implementation Group.
If the procedure is to be implemented or implemented at a later date, the nominated lead must advise Governance, following the NICE Process and the Implementing New Procedures Policy. See OP95 Introduction of New Clinical Techniques and Interventional Procedures

4.3 Assessing the financial implications

Where there is a financial impact regarding implementation of the NICE or National Guidance, a cost assessed action plan and, or a business case or an Implementation of NICE Approved Drugs form (TAGs) (previously referred to as a business case) must be developed. Consideration must be given to potential service redesign, implications for training of staff and purchase of consumables.

The nominated lead is required to work with the Clinical Director, Directorate Manager and Directorate Accountant to assess the cost impact of implementing the guidance.

For NICE TAGs require a business case, refer to Appendix 3 (Implementation of NICE Approved Drugs form)

For any other NICE guidance requiring a business case follow the standard Contract and Commissioning process

The nominated lead must ensure that all NICE Technology Appraisal Guidelines (TAGs) are submitted to Medicines Management Group for formulary process and Trust Management Team for information; this must be in parallel with Contracting and Commissioning Group (CCG) and Wolverhampton Clinical Commissioning Group (WCCG) processes (see Appendix 3).

NICE TAGs, where appropriately applied to the patient population, will be funded by Wolverhampton Clinical Commissioning Group (WCCG) three months from the date of publication. When the delay in an Implementation of NICE Approved Drugs (previously referred to as a business case) has gone beyond 3 months, the commissioner reserves the right to limit retrospective invoicing to 3 months..

5.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources	No
2	Does the implementation of this policy require additional revenue resources	No
3	Does the implementation of this policy require additional manpower	No
4	Does the implementation of this policy release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff	No

6.0 Equality Impact Assessment

This Procedure has been assessed as not affecting the equality and diversity of any one group or person. Implementation of accountabilities and responsibilities applies to all staff.

7.0 Maintenance

It is the responsibility of the Trust NICE Implementation Lead and the Compliance Officers to review the Procedure every 3 years.

8.0 Communication and Training

Communication of this Procedure will be through the following routes:

- Management Team Members to agree and advise all Directorates and Departments of its implementation.
- Trust Intranet policies and procedures available to staff.

9.0 Audit Process

All guidance status will remain partially complaint until the necessary actions have been completed or the guidance has been signed off at Directorate / Divisional / NICE Implementation Group

9.1

Criterion	Lead	Monitoring	Frequency	Committee / Group
National Guidance	Compliance Officers	Central database system	Annually	Quality and Safety Advisory Group
Implementation and response timescales	Governance	Gap analysis/ action plan	Monthly	Divisional / Directorate Governance
National Guidance - Request for closure with monitoring plan	Guidance Lead	Monitoring plan	Quarterly	Quality and Safety Advisory Group Divisional / Directorate Governance
NICE Implementation and response timescales	Compliance Officers Trust NICE Implementation Lead Governance	Central database system NICE reports	Monthly Quarterly Quarterly reports for response status and monthly for exception reports 6 monthly	Divisional Governance meetings NICE Implementation Group (NIG) Directorate Governance meetings Quality and Safety Advisory Group
Exception Report for implementation of Guidance NOT recommended by NICE	Compliance Officer / Trust NICE Implementation Lead	NICE Database central database system NICE reports	As and when	Division NIG Quality and Safety Advisory Group

Criterion	Lead	Monitoring	Frequency	Committee / Group
ALL compliant NICE Guidelines are to be reviewed by Directorate on a risk-based approach to identify NICE guidelines to be included on their annual audit plan/s Audits are to be undertaken within 24 months of achieving compliance. Following being identified as Compliant, all Audits continue to be registered on Clinical Audit Database (CAD)as per process but have a 2-year audit date for all guidance When reviewed as part of the annual audit plan review, any declined audits will have the following rationale added on CAD 'Not considered high risk so no audit planned'	Governance Team Leader(s)/ Trust NICE Implementation Lead	NICE Database Clinical Audit Database	Quarterly review	NIG

Criterion	Lead	Monitoring	Frequency	Committee / Group
Quality Standards will be audited as part of the related NICE Guidance, Clinical Guidance	Governance Team Leader(s) / Trust NICE Implementation Lead	NICE Audit Reports – as part of the Annual Trust Clinical Audit Report	Annually	Quality and Safety Advisory Group/ Clinical Audit Group Directorate/ Divisional Governance meetings NICE Implementation Group (NIG)
NICE status change following an audit outcome of 'moderate non-compliance' or 'significant non-compliance' – must be approved by the NICE guidance Lead and a re-audit undertaken	Governance Support Team Leaders/ Governance Officer		As and when	Divisional Governance NICE Implementation Group (NIG)

10.0 References

RWT Risk Management Assurance Strategy

OP10 Risk Management and Patient Safety reporting Policy

OP 95 Introduction of New Clinical Techniques and Interventional Procedures

Care Quality Commission – Key Lines of Enquiry (KLOE) E1 and E2

NICE Website: **http://www.nice.org.uk/**

Part A - Document Control

Operational Procedure reference: Previously OP56 and OP64 **Version:** 2.1 January 2022	**Operational Procedure Title:** Review and Implementation of NICE Guidance, National Guidance and National Confidential Enquiries Procedure		**Status:** Final	**Author: Trust** Clinical NICE Implementation Lead / Compliance Officers **Chief Officer Sponsor:** Chief Medical Officer
Version / Amendment story	**Version**	**Date**	**Author**	**Reason**
	2.1	Jan 2022	Trust Clinical NICE Implementation Lead	Appendix 3 Implementation of NICE Approved Drugs (Minor amendment to headings Drug costs, Activity cost and Finance approval added)
	2.0	December 2021	Trust Clinical NICE Implementation Lead	Change in NICE audit process Minor wording amendments
	1.3	September 2020	Trust Clinical NICE Implementation Lead	Change to the number of TA NICE audits to be undertaken by Oncology & Haematology Removal of commissioners NICE Assurance Group Minor wording amendments
	1.2	Sept 2019	Trust Clinical NICE Implementation Lead	Change to the number of TA NICE audits to be undertaken by Oncology & Haematology
	1.1	March 2019	Trust Clinical NICE Implementation Lead	Changes to the NICE audit process, Technology Appraisal Guidance (TAG) implementation of NICE approved drugs template and review of divisional exception reports
	1	March 2018	Trust Clinical NICE Implementation Lead	Change from policy OP56 Review and Implementation of NICE Guidance

OP56	V5.2	May 2016	Compliance Officer	NICE TAG Proforma Revised TAG process and financial impact
	V5.1	Dec 2015	Compliance Officer	Updated NICE proforma
	V5	October 2014	Quality Assurance Officer	Scheduled Review
	V4.1	June 2013	Governance Standards Lead	NICE Proforma Appendix 4 updated to include reference to Quality Standards throughout form
	V4	October 2011	Governance Standards Lead	Minor amendment
	V3	October 2009	Governance Standards Lead	Review
	V2	March 2008	Governance Standards Lead	Review
	V1	April 2006	Governance Standards Lead	Introduction

Intended Recipients: All staff	
Consultation Group / Role Titles and Date: **Compliance Oversight Group July 2021/NICE Implementation Group September 2021**	
Name and date of Trust level committee where reviewed	Trust Policy Group – December 2021 Trust Policy Group – Virtual Review January 2022 – Version 2.1
Name and date of final approval committee	Trust Management Committee – January 2022
Date of Procedure issue	January 2022

Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	December 2024 (3 years)

Training and Dissemination:

Communication of this procedure will be through the following routes:

Management Team Members: to agree and advise all Directorates and Departments of its implementation.

Trust Intranet Policies – Available to staff.

Publishing Requirements: Can this document be published on the Trust's public page:

Yes

If yes you must ensure that you have read and have fully considered it meets the requirements outlined in sections 1.9, 3.7 and 3.9 of OP01, Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines, as well as considering any redactions that will be required prior to publication.

To be read in conjunction with:

RWT Integrated Governance Strategy

OP10 Risk Management and Patient Safety Reporting Policy

OP 95 Introduction of New Clinical Techniques and Interventional Procedures

Initial Equality Impact Assessment (All policies): Completed Yes

Full Equality Impact Assessment (as required): Completed Yes / No / NA

If you require this document in an alternative format e.g., larger print please contact Central Governance Department on Ext 5114.

Contact for Review	Trust Clinical NICE Implementation Lead / Compliance Officers
Implementation plan / arrangements (Name implementation lead)	Trust Clinical NICE Implementation Lead / Compliance Officers
Monitoring arrangements and Committee	NICE Implementation Group/ Quality and Safety Advisory Group (QSAG)

Document summary / key issues covered:

This procedure document states the Royal Wolverhampton NHS Trust requirements for review and implementation of NICE and National Guidance

Key words for intranet searching purposes	NICE guidance, National Guidance, NCEPOD
High Risk Policy? **Definition:** • Contains information in the public domain that may present additional risk to the public e.g., contains detailed images of means of strangulation. • References to individually identifiable cases. • References to commercially sensitive or confidential systems. If a policy is considered to be high risk, it will be the responsibility of the author and chief officer sponsor to ensure it is redacted to the requestee	**No**

VALIDITY STATEMENT

This document is due for review on the latest date shown above. After this date, policy and process documents may become invalid. The electronic copy of this document is the only version that is maintained. Printed copies must not be relied upon to contain the latest updates and amendments.

Part B **Ratification Assurance Statement**

Name of document: Review and Implementation of NICE Guidance, National Guidance and National Confidential Enquiries Procedure

Name of author: Dr Ramakrishna Job Title: Trust NICE Lead

I, the above-named author confirms that:

- The Procedure presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as his becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines (OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author: Dr Ramakrishna

Date: 06.10.21

Name of Person Ratifying this document (Chief Officer or Nominee):

Job Title:

Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign, and email this page only to: The Policy Administrator

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and policy version 2.0	**Procedure Title:** **Review and Implementation of NICE Guidance, National Guidance and National Confidential Enquiries Procedure**	
Reviewing Group	NICE Implementation Group Lead	**Date reviewed:** October 2021
Implementation Lead: Dr Ramakrishna		
Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action leads (Timescale for completion)**
Strategy; **Consider** (if appropriate)	N/A	
Training; Consider	N/A	
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed / stored when completed	N/A	
Strategy / Policy / Procedure communication; Consider 1. Key communication messages from the policy / procedure, who to and how?	This is a review so continue communications as before	
Financial cost implementation Consider 1. Business case development	None	
Other specific Policy issues / actions as required **e.g., Risks of failure to implement, gaps or barriers to implementation**	None	

Appendix 1 December 2021

Process for Identification & Implementation of NICE Guidance and National Guidance

NICE Guidance published monthly on NICE website , National Guidance publications scoped monthly (NCEPOD, NCISH, DoH, NHSE, NHSI)

Central Governance issues guidance list to Divisional Medical Director(s) to assess relevance and allocation of Trust leads.

Relevant

Divisional Medical Director allocates appropriate lead and informs Governance

Governance sends email with response timescales plus relevant documents to nominated Lead
Copy of guidance, Appendix 2 TAGs NICE Proforma/process, Appendix 3 Implementation of NICE Approved Drugs Appendix 4 all other guidance NICE proforma, Appendix 5 gap analysis/action plan, Appendix 6 National Guidance Approval for closure/monitoring process

Not Relevant

Divisional Medical Director informs Governance via email

Governance update database with response

Nominated Lead completes relevant NICE/National Guidance documents indicating implementation status, gaps and actions required and returns to Governance within timescales identified. Any risks identified due to non-compliance with the recommendations must be considered for entry onto the appropriate Risk Register (Directorate/Divisional/Trust) and a risk assessment undertaken

NICE Implementation status and action required

Not Applicable

Not Implemented but recommended OR Implemented NOT recommended by NICE

If guidance NOT implemented but recommended OR Implemented and NOT recommended by NICE – nominated Lead must provide rationale and assurance to Division, NICE Implementation Group. An exception report also to be presented a Quality Standards Advisory Group for Implemented but NOT recommended

Compliant

Maintain evidence of implementation & ensure guidance is reviewed and prioritised on a risk based approach for audit within 2 years

Partially compliant (action required)

Provide assurance to Governance of the planned actions with action timescales for implementation

Partially compliant (fully implemented where possible/QS Minimal concern)

Provide assurance to Governance as to the reasons for not being able to fully implement. To be taken to Division for approval of compliant gaps accepted for review in 12 months

National guidance status and action required

Nominated lead to present to directorate and division for approval prior to presenting to Quality Standards Advisory Group

*Monitor actions to completion

Request closure with monitoring plan to division then on approval submit to f Quality Standards Advisory Group or approval of closure

*NICE guidance and national guidance monitoring of action status is via Directorate, Divisional governance meetings and Quality Standards Advisory Group
Governance Officers update database and monitor actions to completion.
Governance to produce compliance status reports to relevant Trust, Division and Directorate committees as appropriate

Appendix 2 **NICE Proforma**

The Royal Wolverhampton NHS Trust

1	**Guidance Title:**		5	**Type of Guidance:**	Technology Appraisals
2	**Guidance No:**		6	**Date of Publication:**	
3	**Lead:**		7	**Date Response due:**	
4	**Directorate:**				

8 The Guideline is:

TECHNOLOGY APPRAISALS (TAGs) ONLY:

☐ ***COMPLIANT - Implementation of NICE Approved Drugs (business case) required**

☐ **COMPLIANT - NICE does not recommend**

*** NICE TAG is approved for clinical use and an Implementation of NICE Approved Drugs form (business case) is required by the Contracting & Commissing Group (C&C) within a month of notification. These business cases should not wait either for the Divisions or Trust Board approval (they are sent to them for notification and not approval). THERE IS A POTENTIAL FOR FINANCIAL RISK IF TIMESCALES ARE BREACHED AND THIS WILL IMPACT ON DIRECTORATES BUDGET**

☐ **NOT IMPLEMENTED**

You are required to provide rationale for submission of an exception report for presentation at Division and NICE Implementation Group

Rationale:	

☐ Alternatives in place - state which and rationale why used over NICE recommendation:

☐ **NOT APPLICABLE**

Select one of the following:

☐ Directorate does not provide this service/procedure - provide rationale:

Rationale:	

☐ Trust does not provide this service/procedure - provide rationale:

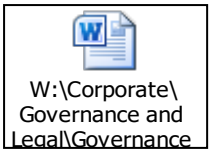
Rationale:	

☐ Patients referred to specialist centres for treatment

Signature/ name of Lead _____ **Date** _____

** Responses MUST be representative of all Trust clinicians affected by the guidance.*

PROCESS MAP - TAGs



Implementation of NICE Approved Drugs

Section 1:		
NICE TA and Description:		
NICE TA Published Date:		
NICE TA Implementation Due Date		
Contact Details of person submitting the case	**Name:**	
	Job Title:	
	Directorate:	
	Tel:	
	Email:	

Section 2:			
Description of what this drug will be used for:			
Is this drug a:	**Replacement**	☐ Yes	☐ No
	If yes, what is this replacing?		
	Alternative option	☐ Yes	☐ No
	If yes, please provide details:		
	New indication:	☐ Yes	☐ No
	Additional option	☐ Yes	☐ No
What is the mode of delivery?	☐ IV ☐ Oral ☐ Other If other, please specify:		
Number of Patients requiring treatment: NB: this is an estimate based on data in the TA and local knowledge	**Current number of patients:**	**Per Year:** Year 1 – Year 2 – Year 3 –	
Are the demographics different to NICE TA estimates?	☐ Yes ☐ No		
	If yes, please explain the reasoning for this:		

Section 3: Drug Costs				
How is this drug dispensed?	☐ **RWT Pharmacy** ☐ **Homecare** ☐ **Boots** ☐ **Other** **If other**, please specify:			
What is the dosage for this drug? *i.e. Timeframe (Cycles or Course)*	***Please show workings out.***			
What is the cost of this drug?	**Per Treatment:**	Per Patient		Total Patients
	Per Year:	Per Patient		Total Patients
Cost of drug being replaced or alternative options (Use average cost if there is more than one option)	Per Treatment:	Per Patient		Total Patients
	Per Year:	Per Patient		Total Patients

Total funding required or savings from drug	Per Treatment:	Per Patient		Total Patients
	Per Year:	Per Patient		Total Patients

Section 4: Activity Costs				
Is there any impact on activity? *i.e. Does this impact on the patient pathway or is this normal standard OP activity.*	☐ **Yes** ☐ **No**			
	If Yes, please provide details by Point of Delivery including tariff and activity impact.			
Is there any revenue (budget) implications? *Internal use only*	☐ **Yes** ☐ **No**			
	If Yes, please provide details:			
Are there any offset costs?	☐ Yes ☐ No			
	If yes, please specify:			
Is this drug a pass through cost to Commissioners?	☐ **Yes** ☐ **No**			
	If Yes, which commissioner: *i.e. CCG or Specialised Services*			
Is there any revenue (budget) implications? *Internal use only*	☐ **Yes** ☐ **No**			
	If Yes, please provide details:			
Numbers of patients per CCG		Year 1	Year 2	Year 3
	Wolverhampton			
	Associated CCGs			
Total funding required/savings per CCG (Activity + Drug costs)	Wolverhampton			
	Associated CCGs			

Section 5: Submission/Sign Off			
Submitted by:	**Clinical Director**	**Matron**	**Manager**
Approved by:	Finance	Date:	
	Contracting and Commissioning Forum	Date:	
	Trust Management Committee	Date:	

Appendix 4 NICE Proforma

The Royal Wolverhampton NHS Trust

1	**Guidance Title:**		5	**Type of Guidance:**	
2	**Guidance No:**		6	**Date of Publication:**	
3	**Lead:**		7	**Date Response due:**	
4	**Directorate:**				

8 The Guideline is:

☐ **COMPLIANT - full implementation**
All aspects of the guidance have been implemented

☐ **PARTIALLY COMPLIANT - actions required**
Select ANY of the following that apply:

☐ Resources Required - Business Case Expected Submission date ☐

☐ Actions Required **(detail in email, gap analysis/action plan, baseline assessment tool or statements)**

☐ *Implementation of new procedure (detail on baseline assessment or action plan)

***For implementation of a new procedure - refer to OP95 Introduction of New Clinical Techniques and Procedures**

☐ **PARTIALLY COMPLIANT - fully implemented where possible**

PARTIALLY COMPLIANT:

☐ Commissioning Input Required State what: ☐

☐ Third party provider input required State what: ☐

☐ **NOT IMPLEMENTED**
Lead must provide assurance to Division and NICE Implementation Group

Rationale: ☐

☐ Alternative Procedures in place - state which and rationale why used over NICE recommendation:

☐ To be reviewed at a later date

☐ **Implementation of Guidance NOT recommended by NICE**
Lead must submit an exception report to Division, NICE Implementation Group and Quality & Safety Intelligence Group

☐ **NOT APPLICABLE**
Select one of the following:

☐ Directorate does not provide this service/procedure

☐ Trust does not provide this service/procedure

☐ Patients referred to specialist centres for treatment

Signature/ name ofLead ☐ **Date** ☐

** Responses MUST be representative of all Trust clinicians affected by the guidance.*

Number of relevant recommendations	0
Number of recommendations met	0
Percentage of recommendations met	

NICE recommendation	Guideline reference	Is the recommendation relevant?	Current activity/evidence	Recommendation met?	Actions needed to implement recommendation	Is there a risk associated with not implementing this recommendation?	Is there a cost or saving?	Deadline	Lead

Statements for Quality Standards

Number of recommendations applicable to the organisation	**0**
Number of recommendations met	**0**
Percentage of recommendations met	

NICE recommendation	Guideline reference	Dates	Key priority for implementation	Is the recommendation relevant to the organisation?	Current activity/evidence	Recommendation met?	Actions needed to implement recommendation	Is there a risk associated with not implementing this recommendation?	Is there a cost or saving?	Deadline	Organisation lead

Appendix 5

Organisational Gap analysis/action plan template

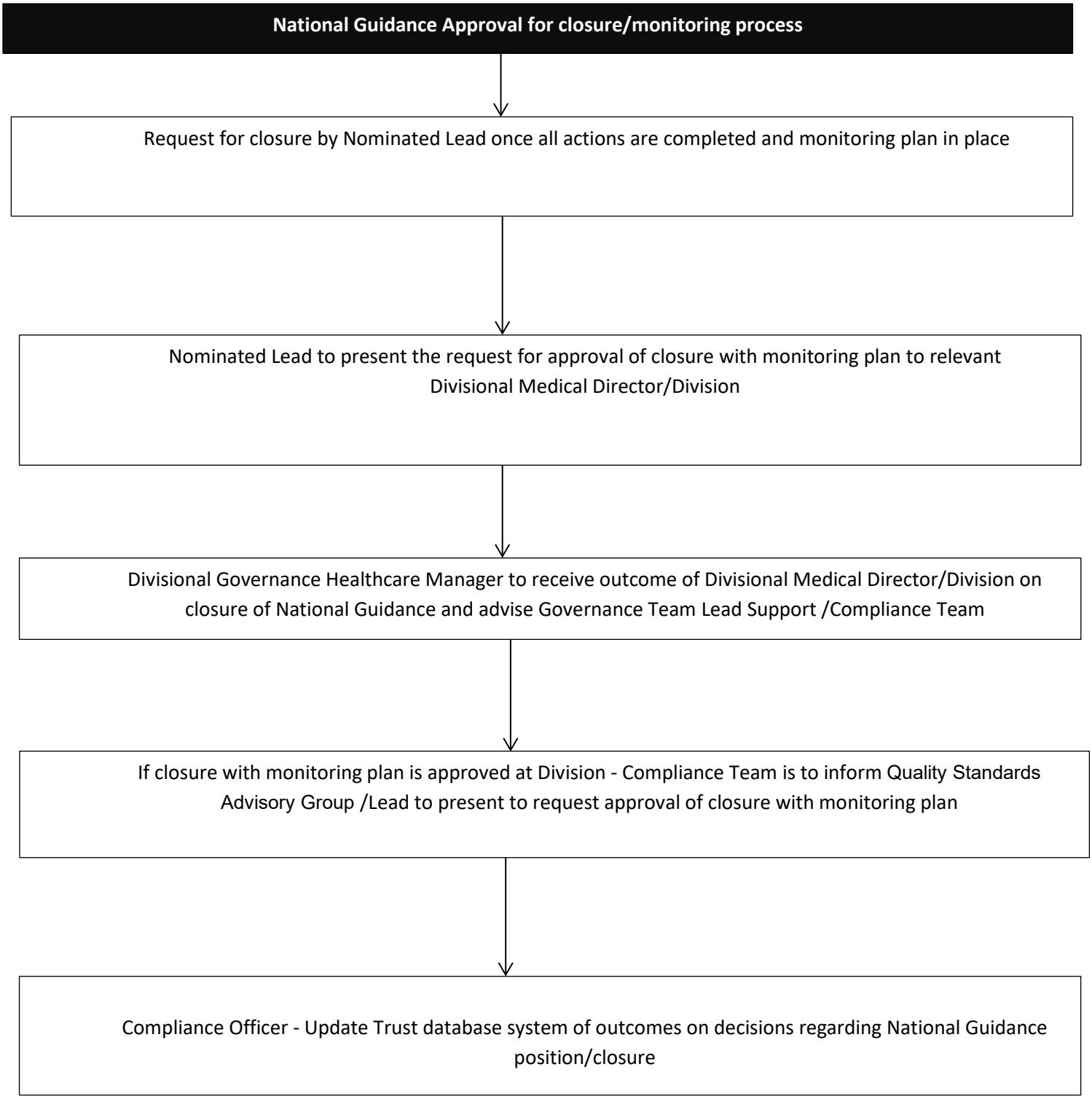
Report Recommendations

The following outlines the recommendations made in the report and the Trust response to them.

NICE/National Guidance Title:	
NICE/National Guidance reference No.	
Date Issued	
Lead	
Directorate	

No	Recommendation	Trust Response	Required Actions (Risk Rating)	Person Responsible	Achievement Due Date	Monitoring process
1.						
2.						
3.						
4.						
5.						
6.	.					
7.						
8.						
9.						
10						

Appendix 6


National Guidance Approval for closure/monitoring process
Request for closure by Nominated Lead once all actions are completed and monitoring plan in place
Nominated Lead to present the request for approval of closure with monitoring plan to relevant Divisional Medical Director/Division
Divisional Governance Healthcare Manager to receive outcome of Divisional Medical Director/Division on closure of National Guidance and advise Governance Team Lead Support /Compliance Team
If closure with monitoring plan is approved at Division - Compliance Team is to inform Quality Standards Advisory Group /Lead to present to request approval of closure with monitoring plan
Compliance Officer - Update Trust database system of outcomes on decisions regarding National Guidance position/closure