

Document information

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Please refer to the internet for the latest version.*

Summary

This policy sets out the CCG approach to considering and implementing NICE guidance, as part of the NICE assurance process of the NHS Wiltshire CCG.

Consultation

This policy was developed in consultation with CCG Clinical Advisory Group. Wider consultation has not been undertaken.

Appendices

The following appendices form part of this document:

Appendix 1: NHS Wiltshire CCG NICE implementation process flow chart

Review Log

Version	Review Date	Reviewed By	Changes Required? (If yes, please summarise)	Changes Approved By	Approval Date
V1.1	11/2/2014	Clinical Advisory Forum	Agreed - for some additional Public Health notes	CCG Governing Body	11/2/2014
V1.1	4/4/2014	Quality and Clinical Governance Committee	Content agreed - for formatting as per WCCG Policy on management of policies and SOPs v2	Quality and Clinical Governance Committee	4/4/2014
V1.2	28/4/2014	TKorhonen CSCSU	Policy formatted to standard template	Quality and Clinical Governance Committee	6/5/2014
V2.1	May 2014	Quality and Clinical Governance Committee	Paragraph inserted regarding alignment of implementation of NICE Guidance with neighbouring CCGs. CAG accountability to be changed from Clinical Executive Team to Quality and Clinical Governance Committee.	Quality and Clinical Governance Committee	
V2.2	February 2016	Emma Higgins and Julie Taggart for the Clinical Advisory Group	May 2014 amendments included. Updated current NICE guidance format. Amended diagram.	Clinical Advisory Group	16.02.16
V2.2	February 2016	Clinical Advisory Group.	Review of proposed amendments and agreement to submit to Quality and Clinical Governance Committee for approval.	Quality and Clinical Governance Committee	08.03.16
V2.3	March 2016	Quality and Clinical Governance Committee	Amendment to opening statement of policy to acknowledge the overarching principles of good practice for community involvement and engagement.	Quality and Clinical Governance Committee Chairs Actions	

Version	Review Date	Reviewed By	Changes Required? (If yes, please summarise)	Changes Approved By	Approval Date
V2.4	April 2016	Clinical Advisory Group	Review of amendments made to specifically include patient engagement.	Clinical Advisory Group – Recommended for final approval by Quality and Clinical Governance Committee	CAG 18.04.16 Q&CGC 05.05.16

Commissioning Policy: Implementation and funding of guidance produced by the National Institute for Health and Care Excellence

1.0 INTRODUCTION AND PURPOSE

The aim of NICE publications is to help the NHS provide high quality care that is consistent across England. NICE produces the following types of guidance documents:

- Guidelines (all types)
- Technology Appraisals
- Interventional Procedures Guidance
- Medical Technologies and Diagnostics Guidance
- Highly Specialised Technologies Guidance

Please refer to the following link for a contemporary list and full detail:

<https://www.nice.org.uk/about/what-we-do>

The following link includes information on the financial and service planning impact

<https://www.nice.org.uk/article/pg1/chapter/1-Introduction-and-background>

Of these publications only technology appraisals are subject to Directions from the Secretary of State; CCGs have a duty to implement them. Given that demand for healthcare is greater than the resources available, prioritisation of competing needs cannot be avoided. At present it is not possible to fully implement all NICE Guidance due to affordability. This situation also applies to guidance issued by other bodies such as clinical guidelines and standards produced by professional bodies. NHS commissioners are entitled to make commissioning policy decisions which do not follow NICE recommendations (other than NICE Technology Appraisals) if they have a good reason to do so. The availability of resources and competing priorities can be good reasons.

The CCG will ensure the overarching principles of good practice for community involvement and engagement, as set out in NICE Guideline NG44, are implemented

<https://www.nice.org.uk/guidance/ng44/chapter/Recommendations#overarching-principles-of-good-practice>

The purpose of the policy is to ensure that NHS Wiltshire CCG has a consistent approach in considering and implementing NICE publications.

2.0 SCOPE AND DEFINITIONS

2.1. SCOPE

This policy applies to any patient for whom the CCG is the responsible commissioner for their NHS care.

2.2. DEFINITIONS

NHS Directions are legally binding instructions to primary care trusts, health authorities, special health authorities and NHS trusts issued by the Secretary of State under section 8 of the National Health Service Act 2006. These now apply to Clinical Commissioning Groups.

Guidance issued to the NHS is non-binding advice which is intended to assist the NHS in the exercise of its statutory duties. It suggests steps which might be taken, factors which could be taken into account and procedures which could be followed to deliver specified steps of administration or policy.

NICE Technology Appraisals are a specific form of Guidance published by NICE which is covered by NHS Directions issued in 2003. The Directions provide that primary care trusts shall make funding available to patients who meet the criteria set out in the Guidance. These now apply to Clinical Commissioning Groups. This funding should be made available within three months from the date that the Technology Appraisal Guidance has been issued unless an extension has been authorised by the Secretary of State.

A treatment which is **efficacious** has been shown to have a beneficial effect in a carefully controlled and optimal environment. However, it is not always possible to have confidence that evidence derived from clinical trials will translate in clinical practice into the anticipated or any meaningful health gain for the target patient population of interest. This is the difference between disease oriented outcomes and patient oriented outcomes. For example a treatment might have demonstrated a change in some physiological factor which is used as a proxy measure for increased life expectancy but this relationship might not be borne out in reality.

Clinical effectiveness is a measure of the extent to which a treatment achieves the pre-defined clinical outcomes in a target patient population.

Cost effectiveness analysis is a method which aims to provide information on value for money. It is not the only method. Cost effectiveness analysis particularly aims to compare very different types of healthcare interventions using a ratio of an intervention's costs versus its benefit.

Responsible Clinical Commissioning Group (CCG) means the CCG which discharges the Secretary of State's functions under the National Health Service Act 2006 for an individual patient.

3.0 PROCESS AND REQUIREMENTS

3.1. NICE Technology Appraisals

NHS Wiltshire CCG will implement NICE technology appraisals in line with the Secretary of State's Directions. The CCG accepts that it has a legal duty to make funding available for treatments recommended in NICE Technology Appraisals within three months to patients whose clinical conditions come within the definitions in the appraisals, unless the Secretary of State makes an exemption. Funding for treatments recommended in NICE Technology Appraisals will receive the highest priority during prioritisation.

3.2 Other NICE guidance

All other NICE guidance is advisory, and will be carefully considered by NHS Wiltshire CCG when developing strategies, planning services and prioritising resources. The CCG reserves the right to depart from NICE guidance, if the CCG has good reason to do so.

3.2.1 Implementation of NICE Clinical Guidelines

NICE clinical guidelines and public health guidelines relate to whole pathways of care and can make a large number of recommendations spanning all stages of care from diagnosis to treatment. In view of their complexity, NICE clinical and public health guidelines are not subject to statutory funding directions, and their local implementation is therefore at the discretion of NHS Wiltshire CCG.

NHS Wiltshire CCG will consider the recommendations in NICE Clinical Guidelines as part of its on-going work to improve the quality of care and health outcomes for the population of Wiltshire.

3.2.2. Implementation of Public Health Guidance

There is an obligation on the part of the CCG to help prevent ill health and enhance health and wellbeing, which is emphasised in NHS England's Longer Lives Project and the publication for Commissioners¹ and in the current 5 Year CCG Plan. NICE Public Health Guidance represents an opportunity to address this by working with Public Health colleagues at Wiltshire Council.

For current and upon the publication of new relevant NICE Public Health (PH) Guidance:

1. Where PH Guidance directly relates to services that the CCG has commissioning responsibilities it will endeavour to facilitate its implementation. Should the CCG be unable to implement such guidance a clear rationale for the decision will be developed and available to partners.
2. For PH Guidance which relates to prevention work in primary and secondary care which is not directly commissioned by the CCG, the CCG will work with Public Health Wiltshire Council as per the MOU to ensure that prevention opportunities are

¹ Our Ambition to Reduce Premature Mortality: A resource to support commissioners in setting a level of ambition (2013): <http://www.england.nhs.uk/ourwork/d-com/prem-mort/>

maximised. We recognise that Public Health will also work directly with Acute Trusts and other agencies with regard to implementing PH Guidance.

3.2.3 Implementation of NICE Interventional Procedures Guidance (IPGs)

The IPG programme assesses the efficacy and safety of interventional procedures, with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce procedures appropriately. NICE IPGs indicate the circumstances in which an intervention might be used and provide a process as to how it might be used (which must be followed if the IPG is implemented). However, NICE IPGs do not make recommendations as to whether the intervention should be used.

The use of any intervention assessed by NICE under their IPG programme is a LOW PRIORITY and not normally funded by NHS Wiltshire CCG unless:

- 1. The intervention has been categorised by NICE as ‘safe and efficacious’ and the clinical governance arrangements have been described as ‘Normal’;**

AND

- 2. Funding has been agreed by commissioners through the funding route detailed below.**

Funding route:

To obtain funding, a business case must be submitted to NHS Wiltshire CCG in advance of the intervention’s use. This requirement applies even if the intervention is included in tariff. Regardless of equivalent cost, NHS Wiltshire CCG will not commission the use of interventions that are less effective or pose a greater risk to patients than standard interventions. Trusts wishing to undertake research associated with the use of IPG interventions must apply for research funds in the usual way.

3.2.4. Implementation of NICE Medical Technologies Guidance (MTGs) and Diagnostic Technologies Guidance (DTGs)

NICE MTGs and DTGs review the clinical and cost impact evidence for a technology compared with currently available technologies. NICE indicates the circumstances in which a technology might be used; MTGs and DTGs do not make recommendations as to whether a technology should be used, and do not override clinical judgement for any individual patient.

The use of any intervention assessed by NICE under their MTG and DTG programmes is a LOW PRIORITY and not normally funded by NHS Wiltshire CCG unless:

- 1. NICE has stated “The case for adoption within the NHS as described is supported by the evidence”**

AND

2. Funding has been agreed by commissioners through either of the funding routes detailed below.

Funding route:

To obtain funding, in advance of the use of a medical or diagnostic technology supported by NICE, the provider must submit a business case to NHS Wiltshire CCG for approval OR NHS Wiltshire CCG agrees to commission the technology following consideration of an evidence review. This approval process applies even if the technology is included in tariff.

3.3. Where NICE Guidance does not exist or is in development

In this circumstance the CCG will follow the current DoH (2006) guidance:

- If a new intervention is not referred to NICE, this does not imply any judgement on whether the intervention(s) in question are clinically effective or cost effective. NHS bodies should continue to use existing arrangements to access the publicly available evidence and to determine local policies for the managed entry of the new intervention. The same principle should apply if an intervention has been referred to NICE but guidance is not yet available at the point at which the new intervention is first introduced.
- In the case of new pharmaceuticals, the New Drugs in development bulletin published by the National Prescribing Centre and Drug Information Pharmacists Group may be a helpful source of information.
- It is not acceptable to cite a lack of NICE guidance as a reason for not providing a treatment. A key role of the NHS is to make decisions about the use of new interventions and this has always been the case, long before NICE was established.
- NICE underpins the decision making processes of the NHS in reaching a decision as to what new interventions are the most appropriate to use and under what circumstances.
- Guidance from NICE exists to provide advice to NHS clinicians, commissioners and patients as to those treatments that are clinically and cost effective. Clinicians are not obliged to follow NICE guidance in every case if they feel that alternative courses of treatment are more appropriate for an individual patient, though they will need to be able to account through clinical governance arrangements for decisions to depart from NICE guidance.
- NICE does not exist to “kite mark” all the interventions which are introduced for use in the NHS and decisions are taken by Ministers against published criteria as to which products NICE should be asked to assess. Not all new interventions will be referred to NICE for appraisal and for those interventions that are referred to NICE there may be a time lag whilst NICE guidance is being developed, though the new NICE Single Technology Appraisal process should help to minimise this lag.
- Therefore, the NHS will have to continue to make informed decisions about the use of these interventions under either circumstance.

(DoH, 2006)

The CCG will use a variety of reputable sources of evidence and information in order to inform their commissioning decision in the absence of NHS Guidance. This will include

robust literature searches and assessment of the quality of evidence available.

4.0 ROLES AND RESPONSIBILITIES

The CCG Medicines Management Team will review Technical Appraisal implementation reporting on issues and exceptions to the Clinical Advisory Group.

The CCG Clinical Advisory Group (CAG) will contribute to dissemination, consideration and monitoring of the implementation of the NICE guidelines and the implementation of the NICE policy in the CCG. Wiltshire CCG commissions services from three Acute Trusts together with neighbouring CCGs. Therefore the CCG, via the CAG, will endeavour to triangulate and implement NICE Guidance in alignment with these neighbouring CCGs. The Clinical Advisory Group is accountable to the CCG's Quality and Clinical Governance Committee

CCG's Quality and Clinical Governance Committee is responsible for ratifying the advisory decisions made by the Clinical Advisory Group.

The Chair of the CCG has ultimate accountability for the strategic and operational management of the organisation, including ensuring all policies are adhered to.

CCG Governing Body has the responsibility for ensuring that there is comprehensive NICE implementation policy and process in place for the CCG.

5.0 TRAINING

No specific training is necessary to support this policy. Any queries relating to policy development should be addressed to the Director of Quality and Patient Safety NHS Wiltshire CCG.

6.0 EQUALITY, DIVERSITY AND MENTAL CAPACITY

An Equality Impact Assessment (EIA) has been completed for this policy and no significant issues were identified. The EIA will be published on the CCG internet. This policy has been assessed and meets the requirements of the Mental Capacity Act 2005.

7.0 SUCCESS CRITERIA/MONITORING EFFECTIVENESS

The evaluation of the effectiveness of this policy will be monitored by the

1. Clinical Advisory Group
 - Bi-monthly review of the action tracker on implementation of NICE guidance and Quality Standards as part of CCG service developments.
 - Bi-monthly reports by the medicines management team on implementation issues or exceptions arising on recommendations for Technology Appraisals by provider organisations.
 - Bi-monthly reports by the Public Health team on any implementation issues or exceptions relating to public health guidance.
 - Assessment of business cases submitted to the Clinical Advisory Group by the provider organisations in regard to implementing new procedures and innovation.
 - Bi-monthly reports of any implementation issues raised by clinicians via the referral management or Individual Funding Request teams.
2. Quality and Clinical Governance Committee
 - Provider performance reports submitted to the Contract Quality review meetings 6/12.
 - Review of annual NICE audits agreed with the provider organisations as per the Quality Schedule.

The implementation of this policy contributes towards CCG assurance regarding the requirements of the NHS Constitution and NHS Litigation Authority Risk Management Standards Risk Management Standard 5 Criterion 8 Best Practice NICE.

8.0 REVIEW

This document may be reviewed at any time at the request of either staff side or management, but will be reviewed after three years.

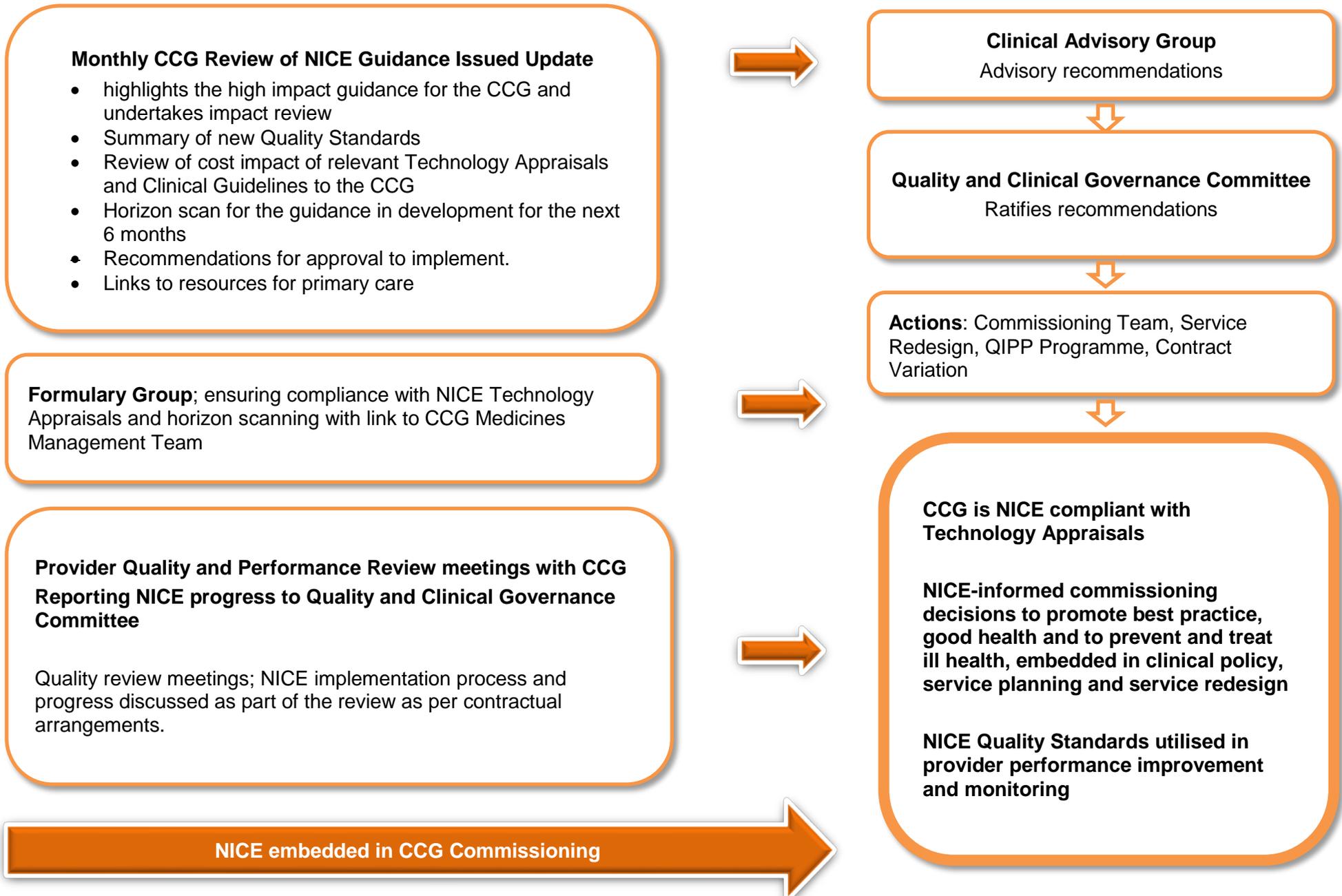
9.0 REFERENCES AND LINKS TO OTHER DOCUMENTS

1. Department of Health Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE) 2010
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Directionsfromthesecretaryofstate/DH_4075685
2. Department of Health (2013) The NHS Constitution for England <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx>
3. NHS Commissioning Board (2013) Commissioning Policy: Implementation and funding of NICE guidance. <http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-05.pdf>

4. Developing NICE Guidelines: the manual October 2014. <https://www.nice.org.uk/article/pmg20/chapter/1%20introduction%20and%20overview>
5. NICE Medicines and prescribing. A comprehensive suite of guidance, advice and support for delivering quality, safety and efficiency in the use of medicines. <https://www.nice.org.uk/about/nice-communities/medicines-and-prescribing>
6. Department of Health (2006), Good Practice Guidance on Managing the Introduction of New Healthcare Interventions and Links to NICE Technology Appraisal Guidance. http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064983

NHS Wiltshire CCG NICE Implementation Process

Appendix 1



Equality Impact Assessment for:

NHS Wiltshire Commissioning Policy: Implementation and funding of guidance produced by the National Institute for Health and Care Excellence (NICE)

1 What's it about?

Refer to equality groups

What's it there for? What's it set up to deliver? What's the proposed change? What do you want to achieve?

This policy document sets out the status of the different types of guidance NICE issues in relation to CCG resource allocation and how the NHS Wiltshire plans to implement them.

The aim of this policy is to support NHS Wiltshire in attainment of its corporate objectives by promoting fair and consistent commissioning decision making across the CCG. It aims to ensure that NHS Wiltshire CCG has a systematic implementation process in place for NICE guidelines. It accepts that NICE guidance represents good clinical practice and effective use of resources.

What potential is there to meet the equality duties?

Potential to eliminate discrimination and promote equal opportunity. This policy will ensure that relevant NICE guidance is considered as part of commissioning plans.

What equality benefits does it create?

Equal access to high quality health care; potentially opens access to new services and treatments and ensures good use of CCG funds by supporting cost-effective commissioning.

What are the barriers to meeting this potential?

Currently clinicians may assume that all NICE guidance is under a legal directive or recommended for implementation. Providers therefore can attempt to introduce treatments without consulting with

Commissioners which is in breach of the NHS Contract. The policy will stop some unproven treatments being available on the NHS and will mean that other more effective interventions will be available to clinicians and their patients

2 Who's it for?

Refer to equality groups

Who is expected to benefit or use the service (internal/external)?

Patients by having NICE guidance and quality standards considered as part of commissioning of local health service provision.

Provider organisations, by having clear guidance for implementation of NICE guidance, and patients, via the commissioned services.

What do you know about them (evidence)?

General population data from NHS Wiltshire (Joint Needs Assessment).

Who is missing or may find it difficult to use the service?

None known.

Do you know why? N/A

3 Impact

Refer to dimensions of equality

How will these services be successfully delivered to a diverse group of people? (positive impact)

Each individual piece of guidance is considered in the context of commissioning services for the relevant protected characteristics. The core concept in each piece of NICE guidance is effectiveness, quality, safety and cost-effectiveness of care.

Is there any innovative thinking, working or technology that could improve delivery?

The policy will be distributed widely via email, intra and internet to provider organisations and the public.

Is there anything about the way you deliver your service which may stop people getting involved? (negative impact) Not aware of any.

Is that reasonable? How can it be justified? How can it be resolved?

N/A

What consultation has taken place?

How has the consultation influenced the service?

Discussion with Wiltshire CCG Clinical Advisory Forum and the Public Health Team Wiltshire Council

4 So what?

Link to business planning process

What changes have you identified? N/A

What will you do now and what will be included in future planning?

Continue to implement the policy.

When will this be reviewed?

How will success be measured?

Assurance process in place to consider NICE guidance as part of commissioning cycle.

Reporting of compliance on implementation of relevant guidance as part of local service provision. Relevant audits carried out by service provider/service lead as necessary.

For the record

Name of person leading this DIA:
Tiina Korhonen CSCSU, Clinical Advisory Forum

Names of people involved in consideration of impact

Date Completed

Name of director signing DIA

Date DIA signed

Date approved by corporate group.