Meeting of Bristol Clinical Commissioning Group

To be held on Tuesday, 29 July 2014
commencing at 1.30 pm in The Vassall Centre,
Fishponds, Bristol

Title: Clinical Policy Review Group update June 2014
Agenda Item: 9

1 Purpose

The aim of this paper is to:

1. Request Board approval of revised policies for:
    - DXA scanning
    - Hernia repair
    - Labiaplasty
    - Rectopexy
    - Homeopathy

2. Request the Board to consider the recommendation from the Clinical Policy Review Group (CPRG) on homeopathy and the wider implications of the homeopathy recommendation from CPRG, and agree a way forward for the commissioning of homeopathy.

2 Background

The following commissioning areas have recently been reviewed by CPRG (please see appendices for the policies):

Policy Name	Suggested Category	Update or New
DXA scanning	Criteria Based Access (CBA)	Update
Hernia repair	CBA (was PA)	Update
Labiaplasty, vaginoplasty, hymenorrhaphy and episiotomy scar revision	Prior Approval (PA)	Update
Rectopexy	Prior Approval (PA)	Re-adoption of an old policy
Homeopathy	IFR	New

Category Descriptions

IFR - Individual Funding Request Panel (not routinely funded, requires panel decision)

CBA - Criteria Based Access (if patient meets criteria, refer directly)

PA - Prior Approval (seek approval from CCG and then refer if evidence provided)

Members are asked to review the policies and also to consider options for implementation (see categories recommended above as either IFR/CBA/PA).

DXA Scanning

Following feedback from the South Gloucestershire Individual Funding Request (IFR) Panel, it was agreed to review the existing DXA Policy. A draft policy was written with clinical input from secondary care and these clinicians were satisfied with the latest version of the policy. The new policy moves to bring the local policy into line with NICE Guidance Document 146. The additional items added to the local policy cover those at the upper age range and those under 40.

The updated policy provides clear guidance on 'monitoring scans' e.g. for patients who have been on medication for a number of years and may be suitable to stop taking medication. The revised policy contains clear timeframes for scans.

The overall financial impact of the revised DXA scan policy was discussed and CPRG proposed that the impact of the policy is to be reviewed after 1 year. CPRG recommended presentation to CCGs for adoption.

Hernia Repair

A policy review was undertaken following local clinician feedback to review the trends in hernia procedure rates, to check whether benchmarking indicates that there was a continued need for a restricted policy and if so, to simplify criteria within the policy.

Public Health advice was that the health community should aim for Standardised Admission Ratios (SARs) for inguinal hernia repair and femoral hernia repair in both elective and non-elective admissions that are not significantly different from the English benchmark (see table below). Adopting a less restrictive policy than that originally agreed in 2011 was supported and the advice given that the impact on activity levels of any change in policy should be monitored.

The table below shows the current SARS for hernia which clearly demonstrate that elective hernia operations are well below the national average, and that non elective hernia is above the national average.

Table 1 SARs for Hernia Operations for BNSSG by elective and non-elective route

CCG	Method of Admission	No. Of Spells	Population	Adjusted for Deprivation			Not Adjusted for Deprivation		
				SAR	Low	High	SAR	Low	High
Bristol CCG	Elective	268	**393760**	48.6	44.8	52.8	48.9	45.0	53.1
	Non Elective	105		133.2	115.4	153.0	134.3	116.4	154.2
Bristol CCG Total		**373**		**58.1**	**54.1**	**62.3**	**58.5**	**54.5**	**62.7**
North Somerset CCG	Elective	248	**175502**	81.5	74.7	88.7	82.6	75.7	90.0
	Non Elective	60		129.0	105.3	156.5	118.7	96.8	143.9
North Somerset CCG Total		**308**		**86.7**	**80.1**	**93.7**	**86.9**	**80.3**	**93.9**
South Gloucestershire CCG	Elective	328	**212558**	83.3	76.8	90.2	83.8	77.3	90.7
	Non Elective	62		142.0	117.5	170.0	126.4	104.6	151.3
South Gloucestershire CCG Total		**390**		**89.3**	**82.9**	**96.0**	**88.6**	**82.3**	**95.3**
BNSSG	Elective	844	**781820**	66.8	63.7	70.0	67.3	64.2	70.6
	Non Elective	227		134.5	122.0	147.9	127.9	116.0	140.8
BNSSG Total		**1071**		**74.1**	**71.0**	**77.3**	**74.3**	**71.1**	**77.5**

A simplified and less restrictive policy was drafted by the IFR team and Public Health and shared with primary and secondary care for comment prior to presentation to CPRG. The reviewed policy recommended by CPRG now covers all types of abdominal and groin hernia other than those explicitly stated as routinely commissioned, and uses one set of criteria rather than different criteria depending on the type of hernia as in the current policy.

CPRG felt that this was a much improved policy and a good articulation of the evidence base. CPRG noted that it was likely that outpatient appointments and elective activity for hernia may increase slightly and that the trusts would need to consider how they would manage this. The group anticipated that there may be a reduction in emergency presentation which often has a longer length of stay than planned treatment. CPRG reflected that practice had changed substantially over the period that the current policy had been in place and that this would also limit inappropriate referrals into secondary care.

CPRG also acknowledged that the move to Criteria Based Access would shift decision making from primary care to secondary care and that secondary care clinicians' specialist skills would be particularly beneficial for assessment for hernia surgery. There was a suggestion that the majority of GPs would not know which hernias are likely to incarcerate.

<u>Labiaplasty, vaginoplasty, hymenorrhaphy and episiotomy scar revision</u>

The reviewed policy recommended by CPRG now explicitly states that prior approval will be needed for cosmetic requests. However is clear that immediate vaginal repair following delivery or revisions post childbirth where there is evidence of pain or discomfort is routinely commissioned as part of obstetric care. CPRG felt this would support consistency of the implementation of the policy, which was an issue identified by IFR panels.

CPRG agreed that to be consistent with other policies, a new bullet point was needed to cover significant functional impairment. This has been added as an extra criterion within the policy. CPRG recommended presentation to CCGs for adoption.

Rectopexy

NHS England took on the commissioning of complex colorectal and complex gynaecological surgery in April 2013, and produced a guide to their commissioning responsibilities called 'The Manual'. The commissioning of rectopexy and STARR was transferred to NHS England in April 2013. However, in the past few months NHS England have advised CCGs that they are not responsible for commissioning all rectopexy and STARR procedures in line with their service specifications in these areas. South West Commissioning Support Unit has been endeavouring to establish for which diagnoses rectopexy and STARR might be a recommended treatment option by local clinicians but would not funded by NHS England, in order that a full evidence review can be undertaken by Public Health and the CCGs can consider if they would wish to fund these interventions for the cohorts of patients identified via CPRG.

As an interim measure, it is recommended that the CCGs re-adopt the old rectopexy and STARR prior approval policy in order that the IFR team can verify that the patients undergoing this intervention but not funded by NHS England have had this treatment recommended by a multi-disciplinary team, and that the patient still has significant functional impairment which needs addressing. The previous CCG policy will only apply to rectopexy and STARR treatments not commissioned by NHS England.

Homeopathy

The Planned Care Leads of the BNSSG CCGs requested that the funding of homeopathy be considered. A briefing paper was prepared by SWCSU to establish the different commissioning options available. Following the report to CCGs on the possible options for homeopathy commissioning, all CCGs came back and asked for a compromise position to be drawn up.

SWCSU met with the homeopathic service and came up with a pragmatic compromise policy that would reduce homeopathic activity by a further 30-50%. This was considered by CPRG, who supported a 'do not commission' policy from a clinical perspective only. They requested that the full briefing paper was considered by CCG, which details the various commissioning options to the CCG Boards, so that the CCGs can make a decision on the commissioning of homeopathy. CPRG were cognisant of the fact that CCGs may for other reasons wish to adopt a different position than their recommendation which is not to routinely fund any homeopathy. The CPRG made their point quite strongly that as a clinical forum they would not support any commissioning of homeopathy due to the weak evidence.

The provider is currently University Hospitals Bristol Foundation Trust who is keen for any policy to be adopted at a much later date, after they have moved this service to a social enterprise model. The service providers would like no change until at least October 2015 in order to guarantee their income to keep their business model viable.

A lack of decision leaves us with a fully commissioned position rather than any limitations at all. If there is not a decision to limit activity with the compromise solution

or to decommission the service, the default position will be that BNSSG continue to commission homeopathy with no restrictions.

3 How have service users, carers and local people been involved?

A member of Healthwatch has been recruited to attend future meetings and was present at the June meeting.

4 Implications on equalities and health inequalities.

Equality impact assessment attached for each of the four revised policies.

Please indicate below the age group/s covered by the service/affected by the issue discussed			
Children/Young People	**X**	**Adults**	**X**

5 Financial Implications

None

6 Legal implications

There are no legal issues raised in this paper

7 How does this fit with Bristol CCG's Annual Work Plan or Strategic Objectives?

The CPRG workplan supports the strategic objectives of ensuring equitable access to healthcare and to work with our partners to ensure there is a sustainable and affordable healthcare system in Bristol.

8 Recommendation(s)

The Board is recommended to approve the revised policies and definition of significant functional impairment.

Alex Layard, IFR Manager (Bristol)
11 July 2014

Martin Jones, Governing Body Member
11 July 2014

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Better health and sustainable healthcare for Bristol

Direct access DXA scanning

Direct access DXA scanning

Document Control

Document Reference	
Title of document	DXA Scanning Policy
Authors name(s)	Paul Freeman/Jon Roberts
Authors job title(s)	Individual Funding Manager/Public Health Consultant
Organisation	SWCSU
Document status	V 0.2
Supersedes	V 0.1
Clinical approval	3/6/14
Discussion and Approval by Clinical Policy Review Group (CPRG)	11/6/14
Discussion and Approval by CCG Boards	
Date of approval	
Publication/issue date	
Review date	
Distribution	Web Site Contract Variation

Version	**Date**	**Status**
Draft v0.1	March 14	Submitted to Clinical Consultees
Draft v0.1	June 14	Submitted to CPRG
Draft v0.2	July 14	Submitted to CCG for final approval
Final v1.0		Issued to Providers in Contract Variation

CATEGORY	Bristol	Criteria Based Access
	North Somerset	Criteria Based Access
	South Gloucestershire	Criteria Based Access

Direct Access DXA scanning to help target treatment in adults at potential risk of osteoporotic (fragility) fracture.

Policy Statement : Date of Issue: XXXX 2014

N.B. If there is no intention to change the patients' treatment based on DXA result, then DXA scanning is not required and will not be routinely funded.

The provision of a DXA scan in the prevention of osteoporotic fragility fractures in adults is not funded by the Commissioner unless patients meet the criteria within this policy.

Direct Access DXA scans are commissioned in patients suspected to be at relatively high risk of fragility fracture where the following criteria are met:

- The patient's absolute risk of having a fracture in the next 10years has been estimated using FRAX or QFracture and assessed as intermediate or high.

Note. For patients above the age limits recognised by the tools, consider patients to be high risk[1]; below the age ranges (<40 years) covered by these tools see the last bullet below, or consider specialist advice.

OR

- Patient had a DXA scan over 5 years ago and a repeat DXA scan would be helpful in re-assessing the need for ongoing treatment

OR

- Patient had a DXA scan over 3 years ago and a repeat DXA scan would be helpful in re-assessing the need to start (or re-start) treatment.

OR

- Patient has received drug treatment for cancer which might have adversely affected bone mineral density (for example aromatase inhibitors or anti-androgen therapy).

OR

- The patient is aged under 40 with a major risk factor for fracture, defined as:
    - A history of multiple fragility fracture
    - History of hip or vertebral fracture
    - Current or recent use of high-dose oral or high-dose systemic glucocorticoids (more than 7.5 mg prednisolone or equivalent per day for 3 months or longer)

Note: Patients assessed as low risk should be reassured that a DXA scan is not necessary and advised on general measures to maintain bone health

In patients whose previous assessment did not lead to treatment and who now require reassessment to judge whether treatment thresholds are now met, fracture risk may be reassessed including DXA scan provided the access criteria in this policy are still met and an interval of at least 3yrs has passed since their last DXA scan.

[1] NICE CG146 –http://www.nice.org.uk/nicemedia/live/13857/60399/60399.pdf

Note: Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. Individual cases will be reviewed at the Commissioner's Individual Funding Request Panel upon receipt of a completed application form from the Patient's GP, Consultant or Clinician. Applications can not be considered from patients personally.

Approved by (committee)	**XXXX**		
Date Approved:	**XXXX**	**Version**	**2**
Produced by (Title)			
Review Date:	**Earliest of either NICE publication or three years from issue.**		

Equality Impact Assessment

1. NAME OF POLICY:

Direct access to DXA Scanning to help target treatment in adults at potential risk of osteoporotic (fragility) fracture policy

2. DETAILS OF LEAD PERSON COMPLETING THIS SCREENING:

Name	**Imran Gilani**
Title	**IFR Coordinator**
Dept/Service	**South West Commissioning Support**
Telephone	**0117 947 4487**
E-mail	**Imran.gilani@swcsu.nhs.uk**

3. PLEASE GIVE A BRIEF DESCRIPTION OF THE SERVICE/POLICY/STRATEGY AND ITS AIMS/OBJECTIVES:

Service/Policy:
The direct access to DXA scanning policy forms part of the Bristol, North Somerset and South Gloucester (BNSSG) Interventions Not Normally Funded (INNF) list.

Aims & Objectives:
The direct access to DXA scanning policy aims to define the criteria for which a patient's symptoms must meet in order for a clinician to request prior approval for assessment for surgical treatment via the Individual Funding Request Team.

4. IS THIS SERVICE/POLICY …

New ☐	**Existing** ☒	**Refreshed** ☐
Joint/Partnership ☐		
If a Joint Partnership, please state the partnership name and lead body:		

5. WHO IS THIS SERVICE/POLICY/STRATEGY LIKELY TO HAVE AN IMPACT ON?

Patients ☒	**Carers** ☐	**Visitors** ☐	**Staff** ☐
Other ☐			

6. WHAT EVIDENCE ARE YOU USING TO INFORM THIS ASSESSMENT?

SOURCE	☒	Date	Details of Evidence [hyperlink to documents]
Demographic (including Census) data		27.06.14	http://www.bristol.gov.uk/sites/default/files/documents/health_and_adult_care/health/JSNA%202012%20Strategic%20Summary%20%28Census%20update%2C.pdf http://www.n-somerset.gov.uk/community/partnerships/Documents/JSNA/Overall%20findings/population%20chapter%20(pdf).pdf http://hosted.southglos.gov.uk/JSNA/South%20Glos%20JSNA%202013%20v4%20050313.pdf
Research Findings		27.06.14	http://publications.nice.org.uk/osteoporosis-assessing-the-risk-of-fragility-fracture-cg146 http://pathways.nice.org.uk/pathways/osteoporosis/fragility-fracture-risk-assessment http://www.nhs.uk/conditions/DEXA-scan/Pages/Introduction.aspx http://www.nhs.uk/conditions/pregnancy-and-baby/pages/pregnancy-and-baby-care.aspx#close http://www.legislation.gov.uk/ukpga/1995/50/section/21 http://www.equalityhumanrights.com/advice-and-guidance/service-providers-guidance/your-responsibilities-when-delivering-services/written-information/ http://www.equalityhumanrights.com/advice-and-guidance/new-equality-act-guidance/equality-act-guidance-downloads/ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/85012/easy-read.pdf https://www.gov.uk/equality-act-2010-

SOURCE	☒	Date	Details of Evidence [hyperlink to documents]
			guidance http://www.nursingtimes.net/Journals/1/Files/2009/7/1/Religion%20or%20belief.pdf
Recent Consultations and Surveys		**27.06.14**	None
Results of: ethnic monitoring data; and any equalities data from the local authority / joint services; or Health inequality data		**27.06.14**	http://www.bristol.gov.uk/sites/default/files/documents/health_and_adult_care/health/JSNA%202012%20Strategic%20Summary%20%28Census%20update%2C.pdf http://www.n-somerset.gov.uk/community/partnerships/Documents/JSNA/Overall%20findings/population%20chapter%20(pdf).pdf http://hosted.southglos.gov.uk/JSNA/South%20Glos%20JSNA%202013%20v4%20050313.pdf
Anecdotal information from groups and agencies within Bristol		**27.06.14**	**None**
Comparisons between similar functions / policies elsewhere		**27.06.14**	http://www.coventryrugbyccg.nhs.uk/Library/Conditions/Articles/dexa-scan/why-is-it-necessary
Analysis of PALS, complaints and public enquires information		**27.06.14** **27.06.14**	**PALS data was reviewed between 22/04/2013 – 22/04/2014. There were no queries received relating to DXA scanning.** **Complaints data was reviewed between dates 01/05/2013 – 01/05/2014. During this period there were no complaints lodged.**
Analysis of audit reports and reviews		**27.06.14**	http://www.southgloucestershireccg.nhs.uk/media/7464/13_06_03_equalities_in_the_new_nhs_ccg.pdf
Other:			**N/A**
None:			

7. ASSESSMENT OF THE EFFECTS OF THE SERVICE/POLICY/STRATEGY ON THE PROTECTED CHARACTERISTICS [EQUALITY GROUPS]

Assess whether the Service/Policy has a positive, negative or neutral impact on the Protected Characteristics.

- ***Positive impact*** *means promoting equal opportunities or improving relations within equality groups*
- ***Negative impact*** *means that an equality group(s) could be disadvantaged or discriminated against*
- ***Neutral impact*** *means that it has no effect currently on equality groups*

Please answer Yes or No in the following table and provide reasons accordingly:

Assessment of Impact of Policy/Service on Protected Characteristics [Equality Groups]				
Protected Characteristic	**Positive Impact** ✓	**Negative Impact** ✓	**Neutral Impact** ✓	**Please provide reasons for your answer and include how it may advance equality of opportunity; eliminate discrimination and foster good relations between different groups**
Age [Children and Young people 0 to 19; Older People 60+]			✓	**The policy has a neutral impact as it applies to all those that meet the criteria, irrespective of a patients age.**
Disability Physical Impairment; Sensory Impairment; Mental Health; Learning Difficulty; Long-Term Condition		✓		**The policy could discriminate as it does not include a statement advising how to obtain alternative formats (to include large print, brail and audio).**
Gender Reassignment [Trans people]			✓	**The policy has a neutral impact, as the policy applies equally to Trans patients.**
Race			✓	**The Black and Minority Ethnic population make up 14.3% of the BNSSG. There are no significant prevalence's between ethnic groups.**

Assessment of Impact of Policy/Service on Protected Characteristics [Equality Groups]				
Protected Characteristic	**Positive Impact** ✓	**Negative Impact** ✓	**Neutral Impact** ✓	**Please provide reasons for your answer and include how it may advance equality of opportunity; eliminate discrimination and foster good relations between different groups**
				As 93% of residents main language is English and 99 % of the resident population of BNSSG can speak English well, the policy can be offered in other languages on request.
Religion or Belief			✓	**The policy has a neutral impact, and considers protected characteristics under the Equality Act 2010**
Sex [Male or Female]			✓	**The policy has a neutral impact, and considers protected characteristics under the Equality Act 2010**
Sexual Orientation [Lesbian, Gay or Bisexual]			✓	**The policy has a neutral impact as it applies to all those who meet criteria, irrespective of a patients sexual orientation.**
Pregnancy & Maternity			✓	**The policy has a neutral impact. Treatment, if required will be carried out as part of the pregnancy care. As such the policy has a neutral impact.**
Marriage & Civil Partnership			✓	**The policy has a neutral impact as a patient's marriage or civil partnership status does not form part of the criteria by which treatment is provided.**

- ***Positive impact*** *means promoting equal opportunities or improving relations within equality groups*
- ***Negative impact*** *means that an equality group(s) could be disadvantaged or discriminated against*
- ***Neutral impact*** *means that it has no effect currently on equality groups*

8. HAVE YOU SET UP THE FOLLOWING:

Attribute	Yes	No	If Yes, please describe what these are, If No, please give reasons.
Equality Monitoring Systems	Yes		Individual funding database, equality information monitoring.
Equality Related Performance Indicators	Yes		IFR key performance indicators and service level agreements.

9. PLEASE EXPLAIN HOW THE RESULTS OF THIS IMPACT ASSESSMENT HAS OR WILL INFLUENCE YOUR SERVICE/POLICY/STRATEGY:

This review has indicated that the policy needs updating to include referral of children, and guidance for users that need the documents in an alternate format.

10. FOR ANY AND EACH NEGATIVE IMPACT IDENTIFIED IN 7 ABOVE, PLEASE ATTACH AN ACTION PLAN TO DEMONSTRATE THE NECESSARY ACTIONS REQUIRED TO EITHER ALLEVIATE/MITIGATE OR REMOVE THE NEGATIVE IMPACT?

Action Plan attached Yes ☒ **No** ☐

11. DATE INITIAL SCREENING COMPLETED: 27TH JUNE 2014

12. REVIEW DATE: 27TH JUNE 2017/REVISED GUIDANCE

Action Plan for Direct access to DXA Scanning to help target treatment in adults at potential risk of osteoporotic (fragility) fracture policy EqIA

Action Plan for				
Potential Areas for action	**Actions**	**Responsible person**	**Timeframe/ target date**	**Evidence and success measures**
Information available in other formats	Add this information to each policy	Imran Gilani	12 Months	Updated policies across BNSSG

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Better health and sustainable healthcare for Bristol

Hernia policy

Document Control

Document Reference	
Title of document	Hernia Management and Repair in Adults
Authors name(s)	Paul Freeman/Chris Hine
Authors job title(s)	Individual Funding Manager/Public Health Consultant
Organisation	SWCSU
Document status	v 0.2
Supersedes	v 0.1
Clinical approval	Via CPRG and feedback prior to CPRG
Discussion and Approval by Clinical Policy Review Group (CPRG)	11 June 2014
Discussion and Approval by CCG Boards	
Date of approval	
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Review date	
Distribution	Web Site Contract Variation

Version	**Date**	**Status**
Draft v0.1	March 14	Submitted to Clinical Consultees
Draft v0.1	June 14	Submitted to CPRG
Draft v0.2	July 14	Submitted to CCG for final approval
Final v1.0		Issued to Providers in Contract Variation

CATEGORY	Bristol	Criteria Based Access
	North Somerset	Criteria Based Access
	South Gloucestershire	Criteria Based Access

Hernia Management and Repair in Adults

Policy Statement : Date of Issue: XXXX 2014

All suspected groin hernias in female patients are approved for referral to secondary care due to the increased risk of incarceration/strangulation.

THIS IS A CRITERIA BASED ACCESS POLICY. REFERRAL TO SECONDARY CARE AND SUBSEQUENT TREATMENT MAY BE PROVIDED WHERE PATIENTS MEET THE CRITERIA BELOW.

- History of incarceration, difficulty in reducing the hernia, or risk of strangulation

OR

- Inguino-scrotal hernia

OR

- Progressive increase in size of hernia (month-on-month)

OR

- Pain or discomfort significantly interfering with activities of daily living, including work related issues e.g. missed work/unable to work/on light duties due to hernia

The commissioner will not fund surgery for the following:

- Small, asymptomatic hernias
- Minimally symptomatic hernias
- Large, wide necked hernias unless there is demonstrable evidence that it is causing significant symptoms
- Groin pain, including ‘athletic pubalgia’, sometimes known as ‘sports hernia’
- Impalpable hernias/abdominal wall weakness

This policy is based on the policy from NW London

www.**northwestlondon**.nhs.uk/_.../23%20**Hernias**%20in%20Adults.pdf

Evidence and Background

An asymptomatic inguinal hernia has been defined as an inguinal hernia without pain or discomfort for the patient, and a minimally symptomatic hernia as an inguinal hernia with complaints that do not interfere with normal daily activities. There is increasing evidence that not all asymptomatic or minimally symptomatic hernias will progress to complication or a state that will require surgical intervention, and many clinicians now agree that watchful waiting is a treatment option. In a few cases the risk of surgery may outweigh the benefit.

Links to Patient Information Leaflets

http://www.southgloucestershireccg.nhs.uk/media/7409/hernia.pdf

Additional information

Obesity and hernia repair. Clinicians have advised that repair is technically more difficult in patients who are obese and the decision to offer surgery needs to take account of this. If an obese patient requires referral for a surgical opinion, it is important to explain that surgery will not automatically be offered.

Patients who are obese should be encouraged and offered support to lose weight.

Advice on hernia prevention should emphasise reducing strain on the abdominal wall: avoid recurrent coughing (smokers should be advised to stop smoking); safe practice in lifting heavy objects; achieve a healthy weight; avoid constipation.

References:

1. Simons MP, Aufenacker T. European Hernia Society guidelines on the treatment on inguinal hernia in adult patients. *Hernia* 2009; 13:343-403

2. Fitzgibbons RJ, Giobbe-Hurder A. Watchful waiting vs. Repar of Inguinal Hernia in Minimally Symptomatic Men. *JAMA* 2006; 295:285292

3. O'Dwyer PJ, Norrie J. Observation or Operation for Patients with an Asymptomatic Inguinal hernia. *Ann Surg* 2006; 244:167-173

4. Regional/PCT Funding Policies reviewed:

a. Bedfordshire and Hertfordshire Priorities forum statement

b. Thames Valley Priorities Committees (Oxfordshire PCTs)

c. West Essex PCT

d. Herfordshire PCT Derbyshire County PCT

e. West Sussex PCT

f. Outer North East London (ONEL)

Note: Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. Individual cases will be reviewed at the commissioner's Individual Funding Request Panel upon receipt of a completed application form from the patient's GP, consultant or clinician. Applications cannot be considered from patients personally.

Approved by (committee)	**XXXX**		
Date Approved:	**XXXX**	**Version**	**2**
Produced by (Title)			
Review Date:	**Earliest of either NICE publication or three years from issue.**		

Equality Impact Assessment

1. NAME OF SERVICE/POLICY/STRATEGY:

Hernia Management and Repair in Adults.

2. DETAILS OF LEAD PERSON COMPLETING THIS SCREENING:

Name	**Imran Gilani**
Title	**IFR Coordinator**
Dept/Service	**South West Commissioning Support**
Telephone	**0117 947 4487**
E-mail	**Imran.gilani@swcsu.nhs.uk**

3. PLEASE GIVE A BRIEF DESCRIPTION OF THE SERVICE/POLICY/STRATEGY AND ITS AIMS/OBJECTIVES:

Service/Policy:
The hernia policy forms part of the Bristol, North Somerset and South Gloucester (BNSSG) Interventions Not Normally Funded (INNF) list.
Aims & Objectives:
The hernia policy aims to define the criteria which a patient's symptoms must meet in order for a clinician to request prior approval for assessment for surgical treatment via the Individual Funding Request Team.

4. IS THIS SERVICE/POLICY …

New ☐	**Existing** ☒	**Refreshed** ☐
Joint/Partnership ☐		
If a Joint Partnership, please state the partnership name and lead body:		

5. WHO IS THIS SERVICE/POLICY/STRATEGY LIKELY TO HAVE AN IMPACT ON?

Patients ☒	**Carers** ☐	**Visitors** ☐	**Staff** ☐
Other ☐			

6. WHAT EVIDENCE ARE YOU USING TO INFORM THIS ASSESSMENT?

SOURCE	☒	Date	Details of Evidence [hyperlink to documents]
Demographic (including Census) data		27.06.14	http://www.bristol.gov.uk/sites/default/files/documents/health_and_adult_care/health/JSNA%202012%20Strategic%20Summary%20%28Census%20update%2C.pdf http://www.n-somerset.gov.uk/community/partnerships/Documents/JSNA/Overall%20findings/population%20chapter%20(pdf).pdf http://hosted.southglos.gov.uk/JSNA/South%20Glos%20JSNA%202013%20v4%20050313.pdf
Research Findings		27.06.14	www.northwestlondon.nhs.uk/_.../23%20Hernias%20in%20Adults.pdf http://publications.nice.org.uk/laparoscopic-surgery-for-inguinal-hernia-repair-ta83/guidance http://www.patient.co.uk/doctor/inguinal-hernias http://www.rcseng.ac.uk/patients/recovering-from-surgery/groin-hernia-repair/who-is-this-leaflet-for/ http://www.nhs.uk/conditions/hernia/Pages/Introduction.aspx http://www.hernia.org/ http://www.legislation.gov.uk/ukpga/1995/50/section/21 http://www.equalityhumanrights.com/advice-and-guidance/service-providers-guidance/your-responsibilities-when-delivering-services/written-information/ http://www.equalityhumanrights.com/advice-and-guidance/new-equality-act-guidance/equality-act-guidance-downloads/ https://www.gov.uk/government/uploads/s

SOURCE	☒	Date	Details of Evidence [hyperlink to documents]
			ystem/uploads/attachment_data/file/85012/easy-read.pdf http://www.herniasolutions.com/about-hernias/types-of-hernias http://www.sharecare.com/health/hernia/are-hernias-more-common-men https://www.gov.uk/equality-act-2010-guidance http://www.maternityaction.org.uk/sitebuildercontent/sitebuilderfiles/pregnancydiscrimination.pdf http://www.nursingtimes.net/Journals/1/Files/2009/7/1/Religion%20or%20belief.pdf
Recent Consultations and Surveys		27.06.14	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3704067/
Results of: ethnic monitoring data; and any equalities data from the local authority / joint services; or Health inequality data		27.06.14	http://www.bristol.gov.uk/sites/default/files/documents/health_and_adult_care/health/JSNA%202012%20Strategic%20Summary%20%28Census%20update%2C.pdf http://www.n-somerset.gov.uk/community/partnerships/Documents/JSNA/Overall%20findings/population%20chapter%20(pdf).pdf http://hosted.southglos.gov.uk/JSNA/South%20Glos%20JSNA%202013%20v4%20050313.pdf
Anecdotal information from groups and agencies within Bristol		27.06.14	None
Comparisons between similar functions / policies		27.06.14	www.northwestlondon.nhs.uk/_.../23%20Hernias%20in%20Adults.pdf http://www.bathandnortheastsomersetccg.nhs.uk/ccg/individual-funding-requests

SOURCE	☒	Date	Details of Evidence [hyperlink to documents]
elsewhere			
Analysis of PALS, complaints and public enquires information		27.06.14 27.06.14	PALS data was reviewed between dates 01/04/2012 – 30/12/2013. There were six relatable queries. These include, exacerbation of symptoms whilst awaiting procedure and general funding criteria. None of this data has identified an inequality issue. PALS data does not include demographic information. The available information has not identified a neutral impact on protected characteristics. Complaints data review (Bristol 01/04/13 - 09/05/14, North Somerset 02/05/13 - 02/05/14 and South Gloucester 01/04/12 - 01/05/14).During this period there were four complaints lodged; these related to post-operative complications, funding refusal and delays in responding. I can confirm no complaints were upheld and a learning outcome was to review the hernia policy. The complaints review highlighted that the policies do not discriminate against protected characteristics.
Analysis of audit reports and reviews		27.06.14	http://www.southgloucestershireccg.nhs.uk/media/7464/13_06_03_equalities_in_the_new_nhs_ccg.pdf
Other:			N/A
None:			

7. ASSESSMENT OF THE EFFECTS OF THE SERVICE/POLICY/STRATEGY ON THE PROTECTED CHARACTERISTICS [EQUALITY GROUPS]

Assess whether the Service/Policy has a positive, negative or neutral impact on the Protected Characteristics.

- ***Positive impact*** *means promoting equal opportunities or improving relations within equality groups*
- ***Negative impact*** *means that an equality group(s) could be disadvantaged or discriminated against*
- ***Neutral impact*** *means that it has no effect currently on equality groups*

Please answer Yes or No in the following table and provide reasons accordingly:

Assessment of Impact of Policy/Service on Protected Characteristics [Equality Groups]				
Protected Characteristic	**Positive Impact** ✓	**Negative Impact** ✓	**Neutral Impact** ✓	**Please provide reasons for your answer and include how it may advance equality of opportunity; eliminate discrimination and foster good relations between different groups**
Age [Children and Young people 0 to 19; Older People 60+]		✓		**This policy is specific to adults and does not include children/young people. There is no alternative policy that specifically relates to children. The policy should outline the management of this service user group.**
Disability Physical Impairment; Sensory Impairment; Mental Health; Learning Difficulty; Long-Term Condition		✓		**The policy could discriminate as it does not include a statement advising how to obtain alternative formats (to include large print, brail and audio).**
Gender Reassignment [Trans people]			✓	**The policy has a neutral impact, as the policy applies equally to Trans patients.**
Race			✓	**The Black and Minority Ethnic population make up 14.3% of the BNSSG. There are no significant prevalence's between ethnic groups.**

Assessment of Impact of Policy/Service on Protected Characteristics [Equality Groups]				
Protected Characteristic	**Positive Impact** ✓	**Negative Impact** ✓	**Neutral Impact** ✓	**Please provide reasons for your answer and include how it may advance equality of opportunity; eliminate discrimination and foster good relations between different groups**
				As 93% of residents main language is English and 99 % of the resident population of BNSSG can speak English well, the policy can be offered in other languages on request.
Religion or Belief			✓	**The policy has a neutral impact, and considers protected characteristics under the Equality Act 2010**
Sex [Male or Female]			✓	**The policy has a neutral impact, Hernias can occur in men or women. Depending on the type of hernia, some occur more in women and some more in men. The policy does not discriminate against either.**
Sexual Orientation [Lesbian, Gay or Bisexual]			✓	**The policy has a neutral impact as it applies to all those who meet criteria, irrespective of a patients sexual orientation.**
Pregnancy & Maternity			✓	**The development of a hernia during pregnancy is not uncommon. Treatment, if required will be carried out as part of the pregnancy care. As such the policy has a neutral impact.**
Marriage & Civil Partnership			✓	**The policy has a neutral impact as a patient's marriage or civil partnership status does not form part of the criteria by which treatment is provided.**

- ***Positive impact*** *means promoting equal opportunities or improving relations within equality groups*
- ***Negative impact*** *means that an equality group(s) could be disadvantaged or discriminated against*
- ***Neutral impact*** *means that it has no effect currently on equality groups*

8. HAVE YOU SET UP THE FOLLOWING:

Attribute	Yes	No	If Yes, please describe what these are, If No, please give reasons.
Equality Monitoring Systems	Yes		Individual funding database, equality information monitoring.
Equality Related Performance Indicators	Yes		IFR key performance indicators and service level agreements.

9. PLEASE EXPLAIN HOW THE RESULTS OF THIS IMPACT ASSESSMENT HAS OR WILL INFLUENCE YOUR SERVICE/POLICY/STRATEGY:

This review has indicated that the policy needs updating to include referral of children, and guidance for users that need the documents in an alternate format.

10. FOR ANY AND EACH NEGATIVE IMPACT IDENTIFIED IN 7 ABOVE, PLEASE ATTACH AN ACTION PLAN TO DEMONSTRATE THE NECESSARY ACTIONS REQUIRED TO EITHER ALLEVIATE/MITIGATE OR REMOVE THE NEGATIVE IMPACT?

Action Plan attached Yes ☒ **No** ☐

11. DATE INITIAL SCREENING COMPLETED: 27TH JUNE 2014

12. REVIEW DATE: 27TH JUNE 2017/REVISED GUIDANCE

Action Plan for Hernia Management and Repair in Adults EqIA

Action Plan for				
Potential Areas for action	**Actions**	**Responsible person**	**Timeframe/ target date**	**Evidence and success measures**
Children and young people	Add information to the policy, outlining the management route for children	Imran Gilani	12 Months	Updated policies across BNSSG
Information available in other formats	Add this information to each policy	Imran Gilani	12 Months	Updated policies across BNSSG

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Labiaplasty, Vaginoplasty, Hymenorrhaphy and Episiotomy Scar Revision Policy

Labiaplasty, Vaginoplasty, Hymenorrhaphy and Episiotomy Scar Revision Policy

Labiaplasty
Labiaplasty is generally a cosmetic procedure to change appearance alone and is not routinely funded. Requests for labiaplasty will be considered for the following indications:

- Where the labia are directly contributing to recurrent disease or infection,
- Where repair of the labia is required after trauma (common consequence of childbirth will not be sufficient reason)
- Where symptoms are causing significant functional impairment*

  * Significant functional impairment is defined by the BNSSG Health Community as:

  - Symptoms preventing the patient fulfilling routine work or educational responsibilities

  - Symptoms preventing the patient carrying out routine domestic or carer activities

Vaginoplasty
Non-reconstructive vaginoplasty or "vaginal rejuvenation" is used to restore vaginal tone and appearance and is not routinely funded. Requests for vaginoplasty will be considered for the following indications:

- Congenital absence or significant developmental/endocrine abnormalities of the vaginal canal,
- Where repair of the vaginal canal is required after trauma (common consequence of will not be sufficient reason).

Hymenorrhaphy
Hymenorrhaphy, or hymen reconstruction surgery, is a cosmetic procedure and is not routinely funded.

Episiotomy Scar Revision
Episiotomy scar revision is a cosmetic procedure and is not routinely funded.

Gender Dysphoria
This policy does not apply to genital reconstruction for gender dysphoria which is covered by the separate policy.

Note: Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy.

Individual cases will be reviewed at the commissioner's Individual Funding Request Panel upon receipt of a completed application form from the patient's GP, consultant or clinician. Applications cannot be considered from patients personally

Equality Impact Assessment

1. NAME OF POLICY:

Labiaplasty, vaginoplasty, hymenorrhaphy and episiotomy scar revision policy

2. DETAILS OF LEAD PERSON COMPLETING THIS SCREENING:

Name	**Imran Gilani**
Title	**IFR Coordinator**
Dept/Service	**South West Commissioning Support**
Telephone	**0117 947 4487**
E-mail	**Imran.gilani@swcsu.nhs.uk**

3. PLEASE GIVE A BRIEF DESCRIPTION OF THE SERVICE/POLICY/STRATEGY AND ITS AIMS/OBJECTIVES:

Service/Policy:
The labiaplasty, vaginoplasty, hymenorrhaphy and episiotomy scar revision policy forms part of the Bristol, North Somerset and South Gloucester (BNSSG) Interventions Not Normally Funded (INNF) list.

Aims & Objectives:
The labiaplasty, vaginoplasty, hymenorrhaphy and episiotomy scar revision policy aims to define the criteria for which a patient's symptoms must meet in order for a clinician to request prior approval for assessment for surgical treatment via the Individual Funding Request Team.

4. IS THIS SERVICE/POLICY …

New ☐	**Existing** ☒	**Refreshed** ☐
Joint/Partnership ☐		
If a Joint Partnership, please state the partnership name and lead body:		

5. WHO IS THIS SERVICE/POLICY/STRATEGY LIKELY TO HAVE AN IMPACT ON?

Patients ☒	**Carers** ☐	**Visitors** ☐	**Staff** ☐
Other ☐			

6. WHAT EVIDENCE ARE YOU USING TO INFORM THIS ASSESSMENT?

SOURCE	☒	Date	Details of Evidence [hyperlink to documents]
Demographic (including Census) data		**27.06.14**	http://www.bristol.gov.uk/sites/default/files/documents/health_and_adult_care/health/JSNA%202012%20Strategic%20Summary%20%28Census%20update%2C.pdf http://www.n-somerset.gov.uk/community/partnerships/Documents/JSNA/Overall%20findings/population%20chapter%20(pdf).pdf http://hosted.southglos.gov.uk/JSNA/South%20Glos%20JSNA%202013%20v4%20050313.pdf
Research Findings		**27.06.14**	http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx http://www.legislation.gov.uk/ukpga/1995/50/section/21 http://www.equalityhumanrights.com/advice-and-guidance/service-providers-guidance/your-responsibilities-when-delivering-services/written-information/ http://www.equalityhumanrights.com/advice-and-guidance/new-equality-act-guidance/equality-act-guidance-downloads/ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/85012/easy-read.pdf https://www.gov.uk/equality-act-2010-guidance http://www.nursingtimes.net/Journals/1/Files/2009/7/1/Religion%20or%20belief.pdf
Recent Consultations and Surveys		**27.06.14**	None
Results of: ethnic		**27.06.14**	http://www.bristol.gov.uk/sites/default/files/documents/health_and_adult_care/health/

SOURCE	☒	Date	Details of Evidence [hyperlink to documents]
monitoring data; and any equalities data from the local authority / joint services; or Health inequality data			JSNA%202012%20Strategic%20Summary%20%28Census%20update%2C.pdf http://www.n-somerset.gov.uk/community/partnerships/Documents/JSNA/Overall%20findings/population%20chapter%20(pdf).pdf http://hosted.southglos.gov.uk/JSNA/South%20Glos%20JSNA%202013%20v4%20050313.pdf
Anecdotal information from groups and agencies within Bristol		27.06.14	None
Comparisons between similar functions / policies elsewhere		27.06.14	http://www.northsomerset.nhs.uk/Services/funding/Policies/Labiaplasty%20Vaginoplasty%20Hymenorrhaphy%20Policy.pdf
Analysis of PALS, complaints and public enquires information		27.06.14 27.06.14	PALS data was reviewed between 22/04/2013 – 22/04/2014. There were no queries received relating to labiaplasty, vaginoplasty, hymenorrhaphy and episiotomy. Complaints data was reviewed between dates 01/04/2013 – 01/04/2014. During this period there were no complaints lodged.
Analysis of audit reports and reviews		27.06.14	http://www.southgloucestershireccg.nhs.uk/media/7464/13_06_03_equalities_in_the_new_nhs_ccg.pdf
Other:			N/A
None:			

7. ASSESSMENT OF THE EFFECTS OF THE SERVICE/POLICY/STRATEGY ON THE PROTECTED CHARACTERISTICS [EQUALITY GROUPS]

Assess whether the Service/Policy has a positive, negative or neutral impact on the Protected Characteristics.

- ***Positive impact*** *means promoting equal opportunities or improving relations within equality groups*
- ***Negative impact*** *means that an equality group(s) could be disadvantaged or discriminated against*
- ***Neutral impact*** *means that it has no effect currently on equality groups*

Please answer Yes or No in the following table and provide reasons accordingly:

Assessment of Impact of Policy/Service on Protected Characteristics [Equality Groups]				
Protected Characteristic	**Positive Impact** ✓	**Negative Impact** ✓	**Neutral Impact** ✓	**Please provide reasons for your answer and include how it may advance equality of opportunity; eliminate discrimination and foster good relations between different groups**
Age [Children and Young people 0 to 19; Older People 60+]			✓	**The policy has a neutral impact as it applies to all those that meet the criteria, irrespective of a patients age.**
Disability Physical Impairment; Sensory Impairment; Mental Health; Learning Difficulty; Long-Term Condition		✓		**The policy could discriminate as it does not include a statement advising how to obtain alternative formats (to include large print, brail and audio).**
Gender Reassignment [Trans people]			✓	**The policy has a neutral impact, as it applies to all those that meet the criteria. (The policy does not apply to genital reconstruction for gender dysphoria which is covered by a separate policy)**
Race			✓	**The Black and Minority Ethnic population make up 14.3% of the BNSSG. There are no significant prevalence's between ethnic groups.**

Assessment of Impact of Policy/Service on Protected Characteristics [Equality Groups]				
Protected Characteristic	**Positive Impact** ✓	**Negative Impact** ✓	**Neutral Impact** ✓	**Please provide reasons for your answer and include how it may advance equality of opportunity; eliminate discrimination and foster good relations between different groups**
				As 93% of residents main language is English and 99 % of the resident population of BNSSG can speak English well, the policy can be offered in other languages on request.
Religion or Belief			✓	**The policy has a neutral impact, and considers protected characteristics under the Equality Act 2010**
Sex [Male or Female]			✓	**The policy has a neutral impact, and considers protected characteristics under the Equality Act 2010**
Sexual Orientation [Lesbian, Gay or Bisexual]			✓	**The policy has a neutral impact as it applies to all those who meet criteria, irrespective of a patients sexual orientation.**
Pregnancy & Maternity			✓	**The policy has a neutral impact. Treatment, if required will be carried out as part of the pregnancy care. As such the policy has a neutral impact.**
Marriage & Civil Partnership			✓	**The policy has a neutral impact as a patient's marriage or civil partnership status does not form part of the criteria by which treatment is provided.**

- ***Positive impact*** *means promoting equal opportunities or improving relations within equality groups*
- ***Negative impact*** *means that an equality group(s) could be disadvantaged or discriminated against*
- ***Neutral impact*** *means that it has no effect currently on equality groups*

8. HAVE YOU SET UP THE FOLLOWING:

Attribute	Yes	No	If Yes, please describe what these are, If No, please give reasons.
Equality Monitoring Systems	Yes		Individual funding database, equality information monitoring.
Equality Related Performance Indicators	Yes		IFR key performance indicators and service level agreements.

9. PLEASE EXPLAIN HOW THE RESULTS OF THIS IMPACT ASSESSMENT HAS OR WILL INFLUENCE YOUR SERVICE/POLICY/STRATEGY:

This review has indicated that the policy needs updating to include referral of children, and guidance for users that need the documents in an alternate format.

10. FOR ANY AND EACH NEGATIVE IMPACT IDENTIFIED IN 7 ABOVE, PLEASE ATTACH AN ACTION PLAN TO DEMONSTRATE THE NECESSARY ACTIONS REQUIRED TO EITHER ALLEVIATE/MITIGATE OR REMOVE THE NEGATIVE IMPACT?

Action Plan attached Yes ☒ **No** ☐

11. DATE INITIAL SCREENING COMPLETED: 27TH JUNE 2014

12. REVIEW DATE: 27TH JUNE 2017/REVISED GUIDANCE

Action Plan for labiaplasty, vaginoplasty, hymenorrhaphy and episiotomy scar revision policy EqIA

Action Plan for				
Potential Areas for action	**Actions**	**Responsible person**	**Timeframe/ target date**	**Evidence and success measures**
Information available in other formats	Add this information to each policy	Imran Gilani	12 Months	Updated policies across BNSSG

NHS
Bristol Clinical Commissioning Group

Better health and sustainable healthcare for Bristol

Rectopexy and STARR policy

Laprascopic Ventral Rectopexy and STARR policy

Policy Statement: Date of Issue: 11 June 2014

This policy relates to laparoscopic ventral rectopexy and STARR in the management of internal rectal prolapse and obstructed defecation syndrome.

Treatment for full thickness prolapse can often present as an emergency and does not require prior approval.

Surgical treatment will only be provided by the NHS for patients meeting criteria set out below:

- Each patient to be considered by a multidisciplinary pelvic floor team, consisting of a gynaecological surgeon, a colorectal surgeon and pelvic floor physiologists and will not be quorate unless a representative from each of these groups is present.
-

AND

The MDT confirms that:

- They recommend this treatment for this patient over all alternatives
- The potential benefit outweighs potential harms
- The MDT is satisfied that the necessary capacity and expertise available to handle this intervention is in place in the proposed delivery setting
-

AND

- Conservative management has been tried and have failed.
  This includes a selection of the following appropriate for the individual:
  Dietary advice; pelvic floor exercises; osmotic and stimulant laxatives; bulking agents and antispasmodics; glycerine and bisacodyl suppositories and biofeedback.

AND

- The patient has unresolved faecal incontinence or obstructed defecation syndrome
-

AND

- Symptoms cause significant functional impairment
-

* Significant functional impairment is defined by the BNSSG health community as:
- Symptoms preventing the patient fulfilling routine work or educational responsibilities
- Symptoms preventing the patient carrying out routine domestic or carer activities.

AND

- The risks, benefits, and side effects of the procedure have been discussed with the patient, and the patient wishes to be considered for this treatment.

If the multidisciplinary team agrees ventral mesh rectopexy or STARR is the most appropriate treatment for the patient's condition, a request for prior approval should be made to the relevant commissioner.

Note: Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. Individual cases will be reviewed at the commissioner's Individual Funding Request Panel upon receipt of a completed application form from the patient's GP, consultant or clinician. Applications cannot be considered from patients personally.

Approved by (committee)	**CPRG**		
Date Approved:	**11 June 2014**	**Version**	**0.1**
Produced by (Title);	**Commissioning Manager – Individual Funding**		
Review Date:	**Earliest of either SHA guidance, NICE publication or three years from issue.**		

Equality Impact Assessment

1. NAME OF SERVICE/POLICY/STRATEGY:

Laparoscopic Ventral Rectopexy and STARR

2. DETAILS OF LEAD PERSON COMPLETING THIS SCREENING:

Name	**Imran Gilani**
Title	**IFR Coordinator**
Dept/Service	**South West Commissioning Support**
Telephone	**0117 947 4487**
E-mail	**Imran.gilani@swcsu.nhs.uk**

3. PLEASE GIVE A BRIEF DESCRIPTION OF THE SERVICE/POLICY/STRATEGY AND ITS AIMS/OBJECTIVES:

Service/Policy:
The laparoscopic ventral rectopexy and STARR policy forms part of the Bristol, North Somerset and South Gloucester (BNSSG) Interventions Not Normally Funded (INNF) list.

Aims & Objectives:
The laparoscopic ventral rectopexy and STARR policy aims to define the criteria for which a patient's symptoms must meet in order for a clinician to request prior approval for assessment for surgical treatment via the Individual Funding Request Team.

4. IS THIS SERVICE/POLICY …

New ☐	**Existing** ☒	**Refreshed** ☐
Joint/Partnership ☐ If a Joint Partnership, please state the partnership name and lead body:		

5. WHO IS THIS SERVICE/POLICY/STRATEGY LIKELY TO HAVE AN IMPACT ON?

Patients ☒	**Carers** ☐	**Visitors** ☐	**Staff** ☐
Other ☐			

6. WHAT EVIDENCE ARE YOU USING TO INFORM THIS ASSESSMENT?

SOURCE	☒	Date	Details of Evidence [hyperlink to documents]
Demographic (including Census) data		17.07.14	http://www.bristol.gov.uk/sites/default/files/documents/health_and_adult_care/health/JSNA%202012%20Strategic%20Summary%20%28Census%20update%2C.pdf http://www.n-somerset.gov.uk/community/partnerships/Documents/JSNA/Overall%20findings/population%20chapter%20(pdf).pdf http://hosted.southglos.gov.uk/JSNA/South%20Glos%20JSNA%202013%20v4%20050313.pdf
Research Findings		17.07.14	http://www.evidence.nhs.uk/search?q=rectal%20prolapse http://www.patient.co.uk/doctor/Rectal-Prolapse.htm http://www.legislation.gov.uk/ukpga/1995/50/section/21 http://www.equalityhumanrights.com/advice-and-guidance/service-providers-guidance/your-responsibilities-when-delivering-services/written-information/ http://www.equalityhumanrights.com/advice-and-guidance/new-equality-act-guidance/equality-act-guidance-downloads/ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/85012/easy-read.pdf https://www.gov.uk/equality-act-2010-guidance http://www.maternityaction.org.uk/sitebuildercontent/sitebuilderfiles/pregnancydiscrimination.pdf http://www.nursingtimes.net/Journals/1/Files/2009/7/1/Religion%20or%20belief.pdf

SOURCE	☒	Date	Details of Evidence [hyperlink to documents]
Recent Consultations and Surveys		**17.07.14**	None
Results of: ethnic monitoring data; and any equalities data from the local authority / joint services; or Health inequality data		**17.07.14**	**http://www.bristol.gov.uk/sites/default/files/documents/health_and_adult_care/health/JSNA%202012%20Strategic%20Summary%20%28Census%20update%2C.pdf** **http://www.n-somerset.gov.uk/community/partnerships/Documents/JSNA/Overall%20findings/population%20chapter%20(pdf).pdf** **http://hosted.southglos.gov.uk/JSNA/South%20Glos%20JSNA%202013%20v4%20050313.pdf**
Anecdotal information from groups and agencies		**17.07.14**	**None**
Comparisons between similar functions / policies elsewhere		**17.07.14**	**http://www.bathandnortheastsomersetccg.nhs.uk/ccg/individual-funding-requests**
Analysis of PALS, complaints and public enquires information		**17.07.14** **17.07.14**	**PALS data was reviewed between dates 22/04/2013 – 22/04/2014. There were no equalities relatable queries received relating to rectopexy.** **Complaints data was reviewed between dates 01/05/2013 – 01/05/2014. During this period there were no complaints lodged.**
Analysis of audit reports and reviews		**17.07.14**	**https://www.southgloucestershireccg.nhs.uk/media/medialibrary/2014/04/equality-information-2014.pdf**
Other:			**N/A**
None:			

7. ASSESSMENT OF THE EFFECTS OF THE SERVICE/POLICY/STRATEGY ON THE PROTECTED CHARACTERISTICS [EQUALITY GROUPS]

Assess whether the Service/Policy has a positive, negative or neutral impact on the Protected Characteristics.

- ***Positive impact*** *means promoting equal opportunities or improving relations within equality groups*
- ***Negative impact*** *means that an equality group(s) could be disadvantaged or discriminated against*
- ***Neutral impact*** *means that it has no effect currently on equality groups*

Please answer Yes or No in the following table and provide reasons accordingly:

Assessment of Impact of Policy/Service on Protected Characteristics [Equality Groups]				
Protected Characteristic	**Positive Impact** ✓	**Negative Impact** ✓	**Neutral Impact** ✓	**Please provide reasons for your answer and include how it may advance equality of opportunity; eliminate discrimination and foster good relations between different groups**
Age [Children and Young people 0 to 19; Older People 60+]			✓	**The policy has a neutral impact, as it applies equally to a patient of any age.**
Disability Physical Impairment; Sensory Impairment; Mental Health; Learning Difficulty; Long-Term Condition		✓		**The policy could discriminate as it does not include a statement advising how to obtain alternative formats (to include large print, brail and audio).**
Gender Reassignment [Trans people]			✓	**The policy has a neutral impact, as the policy applies equally to Trans patients.**
Race			✓	**The Black and Minority Ethnic population make up 14.3% of the BNSSG. There are no significant prevalence's between ethnic groups.** **As 93% of resident's main language is English and 99 % of the resident population of BNSSG can speak English well, the policy can be offered in other languages on request.**

Assessment of Impact of Policy/Service on Protected Characteristics [Equality Groups]				
Protected Characteristic	**Positive Impact** ✓	**Negative Impact** ✓	**Neutral Impact** ✓	**Please provide reasons for your answer and include how it may advance equality of opportunity; eliminate discrimination and foster good relations between different groups**
Religion or Belief			✓	**The policy has a neutral impact, and considers protected characteristics under the Equality Act 2010**
Sex [Male or Female]			✓	**The policy has a neutral impact, and considers protected characteristics under the Equality Act 2010**
Sexual Orientation [Lesbian, Gay or Bisexual]			✓	**The policy has a neutral impact as it applies to all those who meet criteria, irrespective of a patients sexual orientation.**
Pregnancy & Maternity			✓	**Treatment, if required will be carried out as part of the pregnancy care. As such the policy has a neutral impact.**
Marriage & Civil Partnership			✓	**The policy has a neutral impact as a patient's marriage or civil partnership status does not form part of the criteria by which treatment is provided.**

- ***Positive impact*** *means promoting equal opportunities or improving relations within equality groups*
- ***Negative impact*** *means that an equality group(s) could be disadvantaged or discriminated against*
- ***Neutral impact*** *means that it has no effect currently on equality groups*

8. HAVE YOU SET UP THE FOLLOWING:

Attribute	Yes	No	If Yes, please describe what these are, If No, please give reasons.
Equality Monitoring Systems	Yes		Individual funding database, equality information monitoring.
Equality Related Performance Indicators	Yes		IFR key performance indicators and service level agreements.

9. PLEASE EXPLAIN HOW THE RESULTS OF THIS IMPACT ASSESSMENT HAS OR WILL INFLUENCE YOUR SERVICE/POLICY/STRATEGY:

This review has indicated that the policy needs updating to include guidance for users that require documents in an alternate format.

10. FOR ANY AND EACH NEGATIVE IMPACT IDENTIFIED IN 7 ABOVE, PLEASE ATTACH AN ACTION PLAN TO DEMONSTRATE THE NECESSARY ACTIONS REQUIRED TO EITHER ALLEVIATE/MITIGATE OR REMOVE THE NEGATIVE IMPACT?

Action Plan attached Yes ☒ **No** ☐

11. DATE INITIAL SCREENING COMPLETED: 17TH JULY 2014

12. REVIEW DATE: 17TH JULY 2017/REVISED GUIDANCE

Action Plan for laparoscopic ventral rectopexy and STARR policy EqIA

Action Plan for				
Potential Areas for action	**Actions**	**Responsible person**	**Timeframe/ target date**	**Evidence and success measures**
Disability	Add this information to each policy	Imran Gilani	12 Months	Updated policies across BNSSG

Homeopathy Policy Paper

1 Purpose

The purpose of this report is to advise the BNSSG Clinical Commissioning Groups of activity around Homeopathy to July 2013; to present a potential Clinical Commissioning Policy for Homeopathy; to review and agree the Policy; and to consider the timeframe for the implementation of this Policy.

2 Recommendations

The CCG is asked to:

- Note the latest Public Health Review for Homeopathy.
- Note the activity data for Homeopathy.
- Agree the Homeopathy Policy.
- Consider the timeframe for the implementation of this Policy.

3 Background

All Clinical Commissioning Groups (CCG) are required to publish a list of interventions that are not normally funded by the NHS locally. Typically, these will be procedures where there is more limited evidence of clinical or cost effectiveness, or are deemed of lower priority for local resources. A local process is required to ensure that individual clinical and / or personal circumstances can be fully considered where a clinician supports an application being put forward for funding outside of the locally agreed commissioning policy on the basis of exceptional grounds, this is undertaken by the Individual Funding Request Panel.

Amendments to the BNSSG list of Interventions Not Normally Funded (INNF) are agreed through monthly Clinical Commissioning Group (CCG) meetings, after policies have been recommended by the Clinical Policy Review Group.

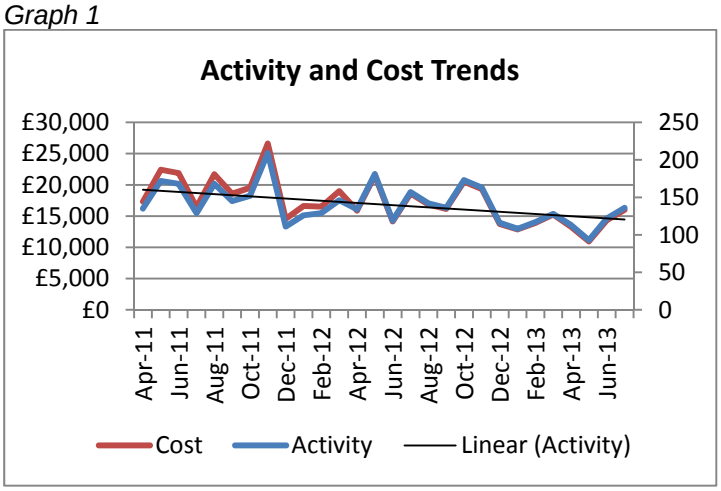
In 2010/11 work with Bristol Homeopathic Hospital was undertaken to review the levels of activity and explore potential for a policy to be introduced around Homeopathy. Whilst there is limited evidence to support homeopathy a policy was worked up that was estimated to reduce new activity for the BNSSG area by 30-50%. Discussions were also held with the service about the follow up ratio, and the optimum number of follow up appointments. However, this policy was not taken through the Commissioning Advisory Group.

4 Activity Report

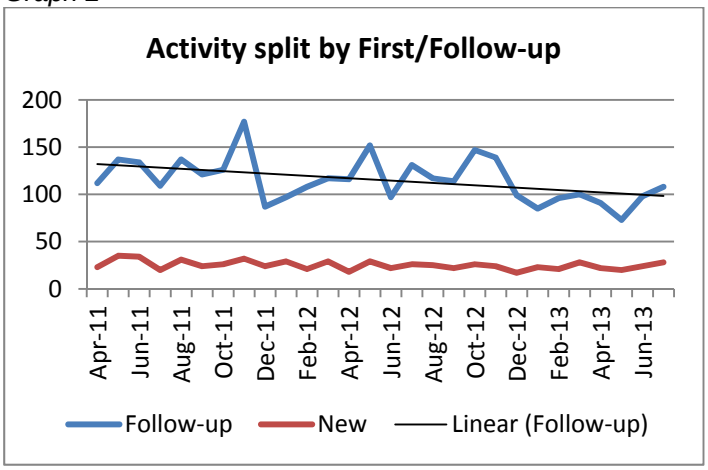
The activity for Homeopathy over the past two full years, and April to July 2013 is presented below with further detail by GP practice provided at Appendix 1.

Homeopathy Activity and Costs for BNSSG at University Hospital Bristol Foundation Trust (UHB) show a decreasing trend from April 2011 to July 2013 (*Graph 1*), and the pattern of Cost and Activity is very close. This is seen across each CCG. The decrease in Activity and Cost is driven by a decrease in follow- up attendances (*Graph 2*).

Graph 1



Graph 2



Bristol CCG has the largest proportion of the Homeopathy Activity across the years and the highest rates, more than double that of S. Glos CCG and N. Somerset CCG (*Table 1*). Bristol CCG has more than double the rates in both First and Follow-up activity.

Table 1 – BNSSG CCGs activity and rates. (Rates based on Population at Mar 2012.)

Activity	Number				Rate per 10,000 pop'n			Proportion		
CCG	11/12	12/13	13/14	13/14 Est.	11/12	12/13	13/14 Est.	11/12	12/13	13/14 Est.
Bristol	1309	1188	351	1034.3	27.4	24.9	21.7	73%	71%	76%
N. Somerset	220	233	57	160.7	10.4	11.0	7.6	12%	14%	12%
S. Glos	261	253	56	153.8	10.1	9.8	6.0	15%	15%	12%
BNSSG	**1790**	**1674**	**464**	**1344.0**	**18.9**	**17.7**	**14.2**	**100%**	**100%**	**100%**

Comparing April -July Activity and Cost figures for 2011/12, 2012/13 and 2013/14 split by CCG, shows that 2013/14 April -July had the lowest Activity and Cost for each CCG in the last 3 years (*Table 2)*. Bristol CCG has seen decreases in in last 2 years, while S. Glos CCG and N. Somerset CCG saw decreases in the last year. S. Glos CCG saw the largest Percentage decrease in 2013/14 April -July.

Table 2 – BNSSG CCGs activity and costs for Period Apr-Jul in 11/12, 12/13, 13/14

CCG	Values	Number 11/12 Apr-Jul	12/13 Apr-Jul	13/14 Apr-Jul	Difference 11/12 to 12/13	12/13 to 13/14	% Difference 11/12 to 12/13	12/13 to 13/14
Bristol	Activity	440	407	351	-33	-56	-7.5%	-13.8%
	Cost	£57,256	£48,284	£41,262	-£8,973	-£7,022	-15.7%	-14.5%
N. Somerset	Activity	73	88	57	15	-31	20.5%	-35.2%
	Cost	£9,405	£10,450	£6,675	£1,045	-£3,775	11.1%	-36.1%
S. Glos	Activity	91	96	56	5	-40	5.5%	-41.7%
	Cost	£11,416	£11,397	£6,576	-£19	-£4,820	-0.2%	-42.3%
BNSSG	Activity	604	591	464	-13	-127	-2.2%	-21.5%
	Cost	£78,077	£70,130	£54,513	-£7,947	-£15,617	-10.2%	-22.3%

Data Period: 2011/12, 2012/13 and 2013/14 Apr-Jul
Data Source: Contract Monitoring Dataset
Definitions: 2013/14 Estimate based on 2011/12 and 2012/13 averaged proportions

5 Public Health Review and Recommendations from Government

The most comprehensive review of Homeopathy was conducted as part of the 2010 House of Commons Science and Technology Committee report on Homeopathy. A critique of this paper (not a critique of the evidence) is provided for consideration in Appendix 2. The summary is as follows:

Summary of report's conclusions and recommendations:

1. The Government should stop allowing the funding of homeopathy on the NHS.

There has been extensive investigation of the effectiveness of homeopathy. There is no good-quality evidence that homeopathy is effective as a treatment for any health condition. No evidence for effectiveness of homeopathy beyond a placebo effect can be demonstrated and the principles on which homeopathy is based are scientifically implausible. As deliberately prescribing a placebo raises ethical issues in the doctor/patient relationship, with the use of placebos risking damaging patients' trust in doctors, the committee recommends that placebos should not be routinely prescribed by the NHS, that the NHS should not fund homeopathic hospitals, and that doctors should not refer patients to homeopaths. Furthermore, by providing homeopathy on the NHS (and allowing MHRA licensing of products) the Government runs the risk of appearing to endorse homeopathy as clinically effective.

2. The Medicines and Healthcare products Regulatory Agency (MHRA) should not allow homeopathic product labels to make medical claims without evidence of efficacy.

3. As they are not medicines, homeopathic products should no longer be licensed by the MHRA. The committee recommends that no homeopathic product licenses are renewed beyond 2013.

The full report is available at House of Commons - Evidence Check 2: Homeopathy - Science and Technology Committee

6 Types of Clinical Commissioning Policy

There are three types of Clinical Commissioning Policy:

Exceptional Funding Policy, where the Commissioner states an intervention is not routinely funded. This means that in order to gain funding the Clinician must make a case that the patient has exceptional circumstances, and therefore warrants funding when others are not routinely funded.

Criteria Based Access Policy, where the Commissioner identifies clear criteria that must be met before a referral is made. Evidence of this is reviewed by audit retrospectively.

Prior Approval Policy, where the Commissioner identifies clear criteria that must be met, and this is checked before a referral can be made. Evidence is collected prospectively.

7 Options for the Clinical Commissioning Groups

The BNSSG CCG's requested work be undertaken to review the commissioning position for homeopathy. This request, was to specifically seek a way forward that allowed some commissioning of homeopathy but that reduced activity for the BNSSG CCG Commissioners. This has been undertaken, and is based upon the work conducted in 2010.

A Policy has been negotiated that means a compromise solution is possible, see Appendix 3 for the Policy. The introduction of this Policy is expected to reduce activity by approximately 30-50% if applied as a Prior Approval, which ensures prospective adherence to the policy, rather than retrospective audit.

Table 1 Summary of the Benefits and Dis-benefits of the Commissioning Options

	Option 1 **Decommission Service**	**Option 2** **Limit Activity with Prior Approval**	**Option 3** **Limit Activity with Criteria Based Access**	**Option 4** **No Change: continue to Commission**
Benefits	This position follows the evidence Base. This position follows the Government guidance. This provides a clear and defendable statement. This allows the service time to change the service to being for privately patients.	This provides some opportunity for patients to be funded by the NHS. This is a compromise position. Those patients using the service may take up more NHS resource by being referred to multiple other services.	This provides some opportunity for patients to be funded by the NHS. This is a compromise position. Those patients using the service may take up more NHS resource by being referred to multiple other services.	This provides opportunity for patients to be funded by the NHS. This policy retains the status quo and is therefore likely to be popular with the current Provider and referrers to the service.
Dis-benefits	This restricts all NHS provision of Homeopathy other than agreed through the Individual Funding Panels in exceptional circumstances. This policy is unlikely to be popular with former users of the service, and those wishing to access the service on the NHS. This policy is unlikely to be popular with the local Providers of the service and those referring to the service. This policy will require public engagement resources.	This position does not follow the evidence base. This position does not follow the Government guidance. The policy would be based on local views, rather than a published evidence base, which could be open to challenge. This policy is unlikely to be popular with the local Providers of the service and those referring to the service. This policy could require public engagement resources.	This position does not follow the evidence base. This position does not follow the Government guidance. The policy would be based on local views, rather than a published evidence base, which could be open to challenge. This policy is unlikely to be popular with the local Providers of the service and those referring to the service. This policy could require public engagement resources.	This position does not follow the evidence base. This position does not follow the Government guidance. The stance would be based on local views, rather than a published evidence base, which could be open to challenge. This policy is unlikely to be popular with some Clinicians who are seeking funding for evidence based services. This stance could require Clinician engagement resources.

8 Financial Implications

Current expenditure on homeopathy is detailed below.

NHS South Gloucestershire

Expenditure on homeopathy in 2012/13 was £29,946. Expenditure in 2011/12 was £32,709, and to July 2013 is £6,576, estimate for this financial year £19,728 based on 4 months activity.

NHS Bristol

Expenditure on homeopathy in 2012/13 was £141,222. Expenditure in 2011/2012 was £169,638, and to July 2013 is £41,262, estimate for this financial year £123,786 based on 4 months activity.

NHS North Somerset

Expenditure on homeopathy in 2012/13 was £27,697. Expenditure in 2011/2012 was £28,805, and to July 2013 is £6,675, estimate for this financial year £20,025 based on 4 months activity.

The financial implications when introducing a Prior Approval Policy are not certain, whilst the policy to reduce but not deter all NHS activity was estimated to reduce new activity by 30-50% in 2010/11, since then activity has seen a slight decline, a less marked effect may therefore be expected, but a decrease would still be anticipated.

Table 2: Summary of the Financial Implications of the Options

	Option 1	Option 2	Option 3	Option 4
Bristol CCG	No saving this financial year due to period of notice, however recurrent savings for 2014/15 onwards. **Estimated saving £123,000 per year**	Based on 30% estimate of Full year 2013/04 estimate. **Estimated saving £37,000 per year.**	Based on 30% estimate of Full year 2013/14 estimate. **Estimated saving £37,000 per year.**	No change. **No saving**
North Somerset CCG	No saving this financial year due to period of notice, however recurrent savings for 2014/15 onwards. **Estimated saving £20,000 per year**	Based on 30% estimate of Full year 2013/14 estimate. **Estimated saving £6,000 per year.**	Based on 30% estimate of Full year 2013/14 estimate. **Estimated saving £6,000 per year.**	No change. **No saving**
South Glos CCG	No saving this financial year due to period of notice, however recurrent savings for 2014/15 onwards. **Estimated saving £18,000 per year**	Based on 30% estimate of Full year 2013/14 estimate. **Estimated saving £6,000 per year.**	Based on 30% estimate of Full year 2013/14 estimate. **Estimated saving £6,000 per year.**	No change. **No saving**

Timeframe for Implementation
Consideration will need to be given to the way in which any new policy is introduced, and how this implementation is undertaken. University Hospitals Bristol Foundation Trust (UH Bristol) are requesting that the implementation of the policy be delayed until 1 April 2016, the following statement from UH Bristol explains the reasons for this,

> *"Consideration will need to be given to the way in which any new policy is introduced, and how this implementation is undertaken. University Hospitals Bristol Foundation Trust (UH Bristol) is working with its Homeopathy service to float the service as a social enterprise in line with guidance and support from the Cabinet Office. The aim of this spin out from UH Bristol is to allow the service to diversify to become a more Integrated Medicine service, with a stronger evidence base for wider services and stronger emerging evidence for the homeopathic service it offers. The Homeopathy service therefore wants to work with commissioners around the access criteria whilst ensuring that the Integrated Medicine offer is discussed with GPs and CCGs to ensure maximum benefit to patients, as well as providing a value for money service to commissioners. The evidence base for Homeopathy can be found at http://www.facultyofhomeopathy.org/research/.*
>
> *The Trust would therefore recommend a deferred implementation of this policy to allow time to establish new services, whilst maintaining an underlying sustainability of the core beneficial functions of the service. This will also allow time for the service to work with commissioners and GPs to ensure that patients who might not be eligible under new access criteria do not present unnecessarily to other specialties and/or become regular attenders with GPs, where UH Bristol feels the relative costs could become higher in some cases."*

9 Legal implications
To provide a reduced service or vary the type of service will require the commissioners to serve a variation to the existing contract. The INNF list is updated throughout the year, and the impact of changes to the INNF list is well understood by the Providers.

10 Implications for health inequalities

The policy is applicable to all.

11 Implications for equalities (Black and Other Minority Ethnic/Disability/Age Issues)

As above.

12 Public involvement

There has been no direct public involvement in the discussion around the development of a Policy for Homeopathy.

Prepared and presented by Claire Beynon, Head of Threshold Management and Individual Funding Requests

Appendices

Appendix 1: Data on Homeopathy by GP Practice

See separate document

Appendix 2 Evidence Base for Homeopathy

Review of "Evidence Check 2: Homeopathy"

Prepared for Commissioning Advisory Forum
March 2010

Summary of report's conclusions and recommendations:

1. The Government should stop allowing the funding of homeopathy on the NHS.

There has been extensive investigation of the effectiveness of homeopathy. There is no good-quality evidence that homeopathy is effective as a treatment for any health condition. No evidence for effectiveness of homeopathy beyond a placebo effect can be demonstrated and the principles on which homeopathy is based are scientifically implausible. As deliberately prescribing a placebo raises ethical issues in the doctor/patient relationship, with the use of placebos risking damaging patients' trust in doctors, the committee recommends that placebos should not be routinely prescribed by the NHS, that the NHS should not fund homeopathic hospitals, and that doctors should not refer patients to homeopaths. Furthermore, by providing homeopathy on the NHS (and allowing MHRA licensing of products) the Government runs the risk of appearing to endorse homeopathy as clinically effective.

2. The Medicines and Healthcare products Regulatory Agency (MHRA) should not allow homeopathic product labels to make medical claims without evidence of efficacy.

3. As they are not medicines, homeopathic products should no longer be licensed by the MHRA. The committee recommends that no homeopathic product licenses are renewed beyond 2013

Introduction

The House of Commons Science and Technology Select Committee published their report "Evidence Check 2: Homeopathy" on 22nd February 2010. This is a cross-party committee made up of 14 MPs appointed by the House of Commons to examine the expenditure, administration and policy of the Government Office for Science. It forms part of their "Evidence Check" programme of work, the purpose of which is to examine how the Government uses evidence to formulate and review its policies.

What is homeopathy?

Homeopathy is a vitalist philosophy; it interprets diseases and sickness as caused by disturbances in a hypothetical vital force or life force. It is based on the theory that 'like cures like', thus treatments must be able to produce symptoms in healthy individuals similar to those of the disease being treated. This stems from observations made by the German physician Samuel Hahnemann who first proposed homeopathy in 1796. He had noted that when he ingested cinchona bark, used as a treatment for malaria, that the effects he experienced were similar to the symptoms of malaria. He therefore reasoned that cure proceeds through similarity. For example, a substance that causes pain in healthy people might be used in a remedy for pain. It is claimed that homeopathy works by stimulating the body's self-healing mechanisms

In homeopathic medicine, remedies become more potent the more they are diluted. Indeed the most potent homeopathic remedies are so diluted that not even a single molecule of the original substance remains in each final preparation. The therapeutic powers of homeopathic remedies are explained by the concept of “water memory”; that water is capable of retaining a "memory" of substances once dissolved in it to arbitrary dilution. Shaking the water at each stage of a serial dilution is claimed to be necessary for an effect to occur.

Why was the review conducted?

This topic was selected for inquiry because the committee was surprised that scientific evidence was not used by Government to formulate the licensing regime operated by the MHRA for homeopathy. The committee decided to broaden the inquiry to include consideration of the evidence base underpinning the Government's policy regarding the funding of homeopathy on the NHS.

Thus fundamentally this inquiry was originally driven by licensing issues rather than concerns over the evidence-base behind provision of homeopathic treatments by the NHS. Furthermore, the inquiry was about **evidence behind <u>governmental policies on homeopathy</u>, not an inquiry into homeopathy itself.**

- **Who was involved?**
- Members of the Committee:
- Phil Willis (*Liberal Democrat, Harrogate and Knaresborough*) (Chairman)
- Dr Roberta Blackman-Woods *(Labour, City of Durham*)
- Tim Boswell (*Conservative, Daventry*)
- Ian Cawsey (*Labour, Brigg & Goole*)
- Nadine Dorries (*Conservative, Mid Bedfordshire*)
- Dr Evan Harris *(Liberal Democrat, Oxford West & Abingdon*)
- Dr Brian Iddon *(Labour, Bolton South East*)
- Gordon Marsden (*Labour, Blackpool South*)
- Dr Doug Naysmith (*Labour, Bristol North West*)
- Dr Bob Spink (*Independent, Castle Point*)
- Ian Stewart (*Labour, Eccles*)
- Graham Stringer (*Labour, Manchester, Blackley*)
- Dr Desmond Turner (*Labour, Brighton Kemptown*)
- Rob Wilson (*Conservative, Reading East*)
-

Process

The process was begun in October 2009 with a call for written evidence on

- Government policy on licensing of homeopathic products;
- Government policy on the funding of homeopathy through the NHS; and
- the evidence base on homeopathic products and services

The committee received around 60 written submissions (most citing references) and also took oral evidence from 2 panels; one focused on NHS funding and provision of homeopathy, the other focused on licensing. However, there was an overlap

between issues raised, particularly around the evidence-base. Additionally oral evidence was taken from the Minister for Health Services, the Chief Scientist and the Department of Health and the Chief Executive of the MHRA

Thus it is clear that the committee discussed evidence from a variety of sources. These include the Department of Health, the British Homeopathic Association, the British Medical Association, Boots, doctors and scientists, NHS trusts, NICE, campaigning groups, and the Advertising Standards Authority. This ranged from level 1 evidence (i.e. randomised controlled trials; systematic reviews, meta-analyses) to level 4 evidence (opinion, anecdote).

Conclusions from evidence submitted

- 1. Explanations for why homeopathy would work are scientifically implausible.

- 2. The evidence base shows that homeopathy is not efficacious.
- This is explored in more detail:

a) Individual scientific studies looking at homeopathy have had positive results. The British Homeopathic Association (BHA) told the committee that "four out of five comprehensive systematic reviews ... have reached the qualified conclusion that homeopathy differs from placebo". However, Professor Edzard Ernst, disputed this claim as two of the positive studies are out of date; one had a positive result but relied on poor-quality studies, one had been re-analysed by its authors and now gave a negative result, and the final study had "very clearly arrived at a devastatingly negative overall conclusion". This final study (*A Shang, K Huwiler-Muntener, L Nartey, P Juni, S Dorig, J A Sterne et al., "Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy", Lancet 2005 366 726–732*) was considered to be the most comprehensive by the committee. This was a systematic review of 110 placebo-controlled trials of homeopathy, and compared the benefits with conventional medicine. After ignoring poor-quality trials (as any well-conducted systematic review should do), the researchers concluded that "there was no convincing evidence that homeopathy was superior to placebo".

b) the BHA put forward a list of studies in support of the effectiveness of homeopathy. However, they had a) "cherry-picked" those conforming to their views and ignored others and b) failed to spot/ignored fundamental flaws in some of these studies

c) evidence from patient satisfaction. Irrespective of what research says, many people value homeopathic therapies and find them helpful. A survey conducted by Bristol Homeopathic Hospital (evidence considered by the committee) found that 70% patients said their health improved after treatment. However, the committee, whilst stating that patient satisfaction is important, concluded that it is not proof that a treatment works.

3. Given that the existing scientific literature showed no good evidence of efficacy that further clinical trials of homeopathy could not be justified.

4. The Government should have a policy on prescribing placebos.

Review of conduct of report

1. This inquiry and resultant report appears to have been rigorously and transparently conducted.
2. The overall conclusions support the evidence presented.
3. However, it is unclear how the call for written evidence was conducted i.e. who was approached, how this call was publicised and there could be an element of selection bias. That said it is extremely unlikely that any level 1–3 evidence would have been missed. To have Prof E Ernst provide oral evidence and to comment on the existing level 1 evidence is a strength as he is the country's leading expert on complementary medicine.
4. Some of the level 4 evidence submitted and considered, both written and oral, contains polemic language. However this appears to apply equally to evidence presented on both sides of the argument and thus it is unlikely that this would have prejudiced the outcome.
5. This inquiry has been conducted rapidly; from the call for written evidence in October 2009 to publication in February 2010. The individual scientific studies cited and presented within written evidence will not have been systematically identified and reviewed for methodological rigour. Thus the committee was dependent upon the integrity of the individuals submitting their personal evidence and that only scientifically robust studies were included in support of any argument. However, given that individuals and organisations representing both sides of the argument were called upon to give evidence, to comment upon each others' evidence and that the scientific rigour of the most important studies was debated and minuted it is unlikely that this will have prejudiced the outcome.

Objections to the report

Supporters of homeopathy have responded to the Science and Technology Committee Report. These objections and responses have been collated by CAMLIS (Complementary and Alternative Medicine Library Information Service; The Royal London Homoeopathic Hospital) and can be found at:
http://www.cam.nhs.uk/news/responses-to-stc-report-on-homeopathy/

Most responses focus on

- the report's approach to the clinical evidence
- the lack of consideration of patients' views
- the absence of any member with an understanding of homeopathy on the committee
- that patient choice should be a consideration in NHS funding issues (but as Professor Ernst put it: "patient choice that is not guided by evidence is not choice but arbitrariness"

The main allegations are centred around:

- lack of consideration of "important evidence". This evidence appears to be patients' testimonies and also evidence from use in animals or very small children, where the placebo effect would be either non-existent or negligible
- The conduct of process of the report; specifically
  - contradictions in statements made by those giving evidence broadly "against" homeopathy
  - the misreporting of statements made by those giving evidence in favour of homeopathy

This leads to their argument that if these inconsistencies exist, then the whole report could be flawed

- a lack of understanding of what homeopathy is and that it transcends science – or at least scientific principles are inappropriate ways of reviewing homeopathy. Thus those supporting homeopathy would attest that a randomised controlled trial (or a systematic review of RCTs) is not an appropriate method of judging effectiveness in homeopathy. This is fundamentally an epistemological and ontological argument. Conventional medicine conforms to the biomedical model which traditionally sits within a positivistic paradigm. Homeopathy has fundamentally different philosophical underpinnings

Homeopathy: Medicine for the 21st Century (H:MC21 UK campaign group for homeopathy) has criticised the report stating that "*the committee has failed to accurately identify even the basic principles of homeopathy, with the result that it cannot claim to have an understanding of the evidence available*." It goes on to suggest that the "*whole Evidence Check was simply a propaganda exercise*" that "*the Commons Science and Technology Committee is not impartial*". H:MC21 urges MPs to "*raise questions about why it was necessary to attack the presence of homeopathy in the NHS, and why it was necessary to do so using such unacceptable standards of investigation*."

Enshrinement of homeopathy in the NHS Act

It appears (anecdotal – websites of homeopathic practitioner's/letters to newspapers etc) that many supporters of homeopathy use this enshrinement as evidence when urging their patients to request the treatment on the NHS – this argument is based upon their right to the treatment through patient choice:

Homeopathy has been available within the NHS since the Health Service first began in 1948. When the NHS Act was originally debated in Parliament, the government confirmed that the homeopathic hospitals would be included in the Health Service and that homeopathy would continue to be available as long as there were "patients wishing to receive it and doctors willing to provide it".

"Evidence Check 2: Homeopathy" acknowledges and makes mention of this enshrinement within its introduction

and also in its conclusions when it states that

154. We welcome the Government's acknowledgement that there is no credible evidence of efficacy for homeopathy, which is an evidence-based view. However, the Government's view has not translated into evidence-based policies.

155. The NHS funds homeopathy and has done so since 1948. We were disappointed that, in light of its view on evidence for homeopathy, the Government has no appetite to review its policies in favour of an evidence-based approach. The Government was reluctant to address the issues of informed patient choice or the appropriateness and ethics of prescribing placebos to patients.

This “mismatch” between the assurance given in 1948 and any change in policy as a result of the select committee’s report will need to be addressed by Government when they make their response.

What happens next?

It is the duty of Government to respond to the committee's report. According to a Member of Parliament I consulted (who sits of the Select Committee for Health) this response should be within 60 days. However, this usual practice may be disrupted by a general election.

Issues for Bristol PCT/wider NHS community to consider

1. The Department of Health told the committee that it “does not maintain a position” on any complementary or alternative therapy. Decisions on use are left to the NHS. PCTs are thus currently free to fund homeopathy. A spokesperson from the Department of Health has been quoted by the BBC as saying: “"Our view is that the local NHS and clinicians, rather than Whitehall, are best placed to make decisions on what treatment is appropriate for their patients - this includes complementary or alternative treatments such as homeopathy."
2. While the Government acknowledges there is no evidence that homeopathy works beyond the placebo effect, it does not intend to change or review its policies on NHS funding of homeopathy.
3. What is “evidence”? As the Chair of the select committee is quoted as saying: “It sets an unfortunate precedent for the Department of Health to consider that the existence of a community which believes that homeopathy works is ‘evidence’ enough to continue spending public money on it.”
4. In 2007 West Kent primary care trust concluded that homoeopathy was not cost effective, which led to the closure of Tunbridge Wells Homeopathic Hospital. An investigation last year by Channel 4 television’s More4 News found that at least nine other primary care trusts do not fund homoeopathy. The committee recommends that the health department circulate the review of homoeopathy conducted by West Kent to other trusts with homoeopathic hospitals in their area.

Quote from Dr Ben Goldacre:
“*Homeopaths can’t expect special treatment among all forms of medicine, if the evidence actively shows it doesn’t work, then that’s that*.”

Prepared by Public Health March 2010, no change to this evidence since 2010 confirmed in September 2013

Appendix 3 : Clinical Commissioning Policy for Homeopathy (Prior Approval)

Policy Statement [*pending ratification*]: Date of Issue: XXXX 2014

The CCG has accepted that there are some circumstances where the referring Clinician and their patient consider homeopathic management to be the appropriate means of managing their health condition. All requests to fund such referrals will be assessed individually and evidence of clinical effectiveness will be taken into account. Prior Approval must be gained before referring. Requests will be assessed for funding if the following criteria are met:

1. Severity of the Unresolved Health Issues

Where the patient has a significant condition which causes the patient significant health problem(s) which have a severe impact on quality of life, defined as:

- Symptoms prevent the patient fulfilling routine work or educational responsibilities, or
- Symptoms prevent the patient carrying out routine domestic or carer activities
- Or where the patient is a child with significant health problems, significantly affecting family life.

AND

2. Treatment Options

Where the condition has not been helped by conventional treatment, **OR**
Where conventional treatment is contraindicated, **OR**
Where conventional treatment is unacceptable to the patient and no acceptable alternative is available **OR**
Treatment of side effects of mainstream treatments or medications that would otherwise mean mainstream treatment would cease e.g. cancer treatments

NOTE: Homeopathy is **NOT** commissioned for patients with conditions where the standard commissioned treatment is undertaken in primary care e.g. : facial blushing/ hot flushes, low back pain, mild/moderate cough, allergies, rhinitis (chronic or seasonal), menopausal problems, musculoskeletal pain, insomnia/ interrupted or unsatisfactory sleeping patterns, receding gums, hyperhidrosis.

One new appointment and up to three follow up appointments are commissioned for each patient when funding is agreed. Further follow-up appointments would need to be agreed via the prior- approval process. Re-referrals within two years of referral will not be expected.

These criteria have been influenced by:

(a) Work with the Homeopathy service locally
(b) A list of evidence for the effectiveness of homeopathic medicine for some illnesses (*http://www.facultyofhomeopathy.org/research/*); and
(c) The fact that Commissioners have to prioritise mainstream treatments for which there is strong evidence of effectiveness.

Developed in Collaboration with Dr Elizabeth Thompson - Lead Consultant Homeopathic Physician and Honorary Senior Lecturer in Palliative Medicine, University Hospital Bristol.

BNSSG Homeopathy activity at UHB

Notes:

Data Source	*Contract Monitoring Dataset*
	Registered population - Exeter via PCIS
Data Period	*2011/12, 2012/13 and 2013/14 Apr-Jul*
Broken Down E	*Financial Year, GP Practice, Trust*
Definitions	*2013/14 Estimate based on 2013/14 Ap-Jul multiplied up to 12 months (*3)*
	New OP used as a proxy for referral

BNSSG GP Practices split by financial year, for New/First Homeopathy OP appointments

F_WTYP	New

Activity			Fin Year			
CCG	GP_PRACT	Practice	2011/2012	2012/2013	2013/2014	Grand Total
Bristol	**L81012**	Montpelier Health Centre	21	26	6	53
	L81061	The Wellspring Surgery	20	19	3	42
	L81090	The Family Practice	11	22	7	40
	L81015	Seymour Medical Practice	21	9	2	32
	L81091	Whiteladies Medical Group	11	10	6	27
	L81082	Bedminster Family Practice	10	9	5	24
	L81112	Bishopston Medical Practice	12	5	2	19
	L81633	Clifton Village Practice	11	4	2	17
	L81081	Pembroke Road Surgery	6	7	4	17
	L81033	Nightingale Valley Practice	8	4	4	16
	L81078	Gloucester Road Medical Centre	5	7	2	14
	L81125	Wells Road Surgery	7	4	1	12
	L81092	The Easton Family Practice	8	3	1	12
	L81013	Fishponds Family Practice	6	4	2	12
	L81035	The Malago Surgery	3	6	2	11
	L81007	The Southville Surgery	4	6	1	11

L81087	Beechwood Medical Practice	5	3	2	10
L81038	Air Balloon Surgery	3	5	2	10
L81089	Lawrence Hill Health Centre	4	4	1	9
L81075	The Old School Surgery	3	4	2	9
L81084	Priory Surgery	4	4		8
L81023	Eastville Medical Practice	3	3	2	8
L81008	Shirehampton Group Practice	4	3		7
L81622	Helios Medical Centre	2	2	3	7
L81131	Fallodon Way Medical Centre	3	1	3	7
L81057	Gaywood House Surgery	7			7
L81107	Nevil Road Surgery	4	1	1	6
L81648	The Maytrees Practice	2	4		6
L81022	Horfield Health Centre	3	3		6
L81077	Sea Mills Surgery	2	3	1	6
L81656	Hotwells Surgery	4	1		5
L81067	Southmead And Henbury Family Practice	4	1		5
L81120	Birchwood Medical Practice	2	2		4
L81017	Westbury-On-Trym Surgery	2	2		4
L81031	The Armada Family Practice	2	2		4
L81093	St Martins Surgery	3		1	4
L81037	Bradgate Surgery		2	1	3
L81095	The Crest Family Practice	1		2	3
L81133	Student Health Service	3			3
L81009	Stockwood Medical Centre		2	1	3
L81062	St George Health Centre	1	1	1	3
Y02578	Broadmead Medical Centre	2	1		3
L81032	The Wedmore Practice	2	1		3
L81663	Sneyd Park Surgery	2			2
L81099	Ridingleaze Medical Centre	1	1		2
L81094	The Merrywood Practice	1	1		2
L81053	The Lennard Surgery	2			2
L81054	Grange Road Surgery	2			2
V81999	Practice Code Is Not Known		1	1	2

Bristol	**L81083**	Hartwood Healthcare	1	1		2
	Blank	#N/A	1			1
	L81669	Monks Park Surgery		1		1
	L81088	Lodgeside Surgery		1		1
	L81098	Greenway Communtiy Practice	1			1
Bristol Total			**250**	**206**	**74**	**530**
North Somers	**L81056**	Long Ashton Surgery	10	5	1	16
	L81060	Backwell And Nailse Medical Group	6	6	1	13
	L81004	Portishead Medical Group	4	6	1	11
	L81040	Clevedon Riverside Group	5	3	1	9
	L81044	Tudor Lodge Surgery	3	2	1	6
	L81021	Winscombe Surgery	3	2		5
	L81102	Sunnyside Surgery	1	4		5
	L81600	Harbourside Family Practice	3	2		5
	L81074	Yeo Vale Medical Practice	3	2		5
	L81119	Clarence Park Surgery	1	3		4
	L81086	Wrington Vale Medical Practice	1	1	1	3
	L81034	Nailsea Family Practice	2			2
	L81085	Heywood Family Practice	1		1	2
	L81116	The Green Practice		2		2
	L81643	The Cedars Surgery		1	1	2
	L81124	Riverbank Medical Centre	1	1		2
	L81002	The Village Surgery		1		1
	L81670	The Locality Health Centre	1			1
	L81016	Graham Road Surgery		1		1
	L81058	The Milton Surgery		1		1
	Y02581	St Georges Surgery	1			1
	V81999	Practice Code Is Not Known			1	1
	L81051	New Court Surgery	1			1
North Somerset Total			**47**	**43**	**9**	**99**
South Glos	**L81079**	Hanham Surgery	1	7	2	10
	L81014	Frome Valley Medical Centre	2	4		6
	L81055	The Orchard Medical Centre	5	1		6

	L81024	Courtside Surgery	1	3	1	5
	L81028	Northville Family Practice	4		1	5
	L81632	Emersons Green Medical Centre	1	3	1	5
	L81047	West Walk Surgery	2	2	1	5
	L81052	The Willow Surgery	3	1	1	5
	L81118	Stoke Gifford Medical Centre	1	2	1	4
	L81019	The Concord Medical Centre	2	1	1	4
	L81130	The Park Medical Practice	1	1		2
	L81029	Three Shires Medical Practice	1	1		2
	L81018	Thornbury Health Centre - Burney	1		1	2
	L81127	Almondsbury Surgery		1	1	2
	L81649	Bradley Stoke Surgery	1	1		2
	L81046	Leap Valley Surgery	1	1		2
	L81106	Thornbury Health Centre - Male		1		1
	Y02553	The Orchard Medical Centre Apms	1			1
	L81103	St Mary Street Surgery		1		1
	L81063	Kingswood Health Centre	1			1
	L81050	Close Farm Surgery	1			1
	L81026	Christchurch Family Medical Centre	1			1
	L81036	Coniston Medical Practice S		1		1
South Glos Total			**31**	**32**	**11**	**74**
Grand Total			**328**	**281**	**94**	**703**