



*Aylesbury Vale Clinical Commissioning Group
Bracknell and Ascot Clinical Commissioning Group
Chiltern Clinical Commissioning Group
Newbury and District Clinical Commissioning Group
North and West Reading Clinical Commissioning Group
Oxfordshire Clinical Commissioning Group
South Reading Clinical Commissioning Group
Slough Clinical Commissioning Group
Windsor, Ascot and Maidenhead Clinical Commissioning Group
Wokingham Clinical Commissioning Group*

Thames Valley Priorities Committee

Minutes of the meeting held Wednesday 1st February 2017

Conference Room B, Oxfordshire CCG, Jubilee House, 5510 John Smith Drive, Oxford OX4 2LH

In Attendance:

Alan Penn	Lay Member Chair	Thames Valley Priorities Committee
Tiina Korhonen	Clinical Effectiveness Lead	SCWCSU
Laura Tully	Clinical Effectiveness Lead	SCWCSU
Kate Forbes	Clinical Effectiveness Manager	SCWCSU
Kathryn Markey	Clinical Effectiveness Manager	SCWCSU
Rachel Finch	Clinical Effectiveness Administrator	SCWCSU
Lindsey Barker	Medical Director	Royal Berkshire NHS Foundation Trust
Dr Tony Berendt	Medical Director	Oxford University Hospitals NHS Trust
Miles Carter	West Oxfordshire Locality Clinical Director	Oxfordshire CCG
Linda Collins	NICE Lead	Oxfordshire CCG
Dr Graham Jackson	Clinical Chair	Aylesbury Vale CCG
Dr Megan John	GP	Berkshire East CCGs
Catriona Khetyar	Head of Medicines Optimisation	Berkshire East CCGs
Philip Murray	Chief Finance Officer	Chiltern & Aylesbury Vale CCGs
Professor Chris Newdick	Special Advisor – Health Law	University of Reading
Dr Anees Pari	Senior Public Health Registrar	Bracknell Forest Council
Sarah Robson	Head of IFR	SCWCSU
Dr Mark Sheehan	Special Advisor - Ethics	University of Oxford

Topic Specialists in Attendance for Agenda Items:

Clare Jeffery	Lead MRI Radiographer	Royal Berkshire Hospital
Mr Tom Pollard	Consultant Orthopaedic Surgeon	Royal Berkshire NHS Foundation Trust
Mr Daniel Rolton	Consultant Spinal Surgeon	Royal Berkshire NHS Foundation Trust
Dr Hazel Needham	Consultant Community Paediatrician	Royal Berkshire NHS Foundation Trust
Catherine Greaves		

Apologies:

Frances Fairman	Medical Director – Clinical Strategy	NHS England – South Central
Fiona Slevin-Brown	Director of Strategy & Operations	Berkshire East CCGs
Jane Butterworth	Associate Director of Long Term Conditions & Medicines Management	Aylesbury Vale CCG & Chiltern CCG
Mark Hancock	Medical Director	Oxford Health NHS Trust
Lalitha Iyer	Medical Director	Berkshire East
Tracey Marriot	Director of Innovation Adoption	Oxford Academic Health Science Network
Dr Clive Meux	Medical Director	Oxfordshire Health NHS Foundation Trust
Eleanor Mitchell	Operations Director	Berkshire West CCGs
Dr Minoo Irani	Medical Director	Royal Berkshire NHS Foundation Trust
Jeremy Servian	IFR Manager	Oxfordshire CCG
Rosalind Pearce	Executive Director HealthWatch	Oxfordshire
Cathy Winfield	Chief Officer	Berkshire West CCGs

1.0	Welcome & Introductions
1.1	The Chair opened the meeting and welcomed members of the Committee.
2.0	Apologies for Absence
2.1	Recorded as above. This meeting was not quorate. Action: Clinical Effectiveness team to circulate minutes detailing any policy recommendations made by the Committee to absent members for approval (Berkshire West CCGs).
3.0	Declarations of Interest
3.1	None were declared.
4.0	Draft Minutes of the Priorities Committee meeting held 23rd November 2016 (Paper 16-086) – Confirm Accuracy The draft minutes were accepted as a true record of the meeting.
4.1	Committee update
4.1.1	Phillip Murray advised that he will no longer attend the Committee from March; the Committee expressed their thanks for his valued contribution. Phillip suggests he is replaced by a member from Oxfordshire CCG and offered to make contact with Gareth Kenworthy in the first instance to seek representation.
4.1.2	The Committee welcomed Kate Forbes who has joined the Clinical Effectiveness team as Clinical Effectiveness Manager.
5.0	Draft Minutes of the Priorities Committee meetings – Matters Arising
5.1	Minutes of the Priorities Committee held in May 2016, Action 10.1 – Fertility care pathway - CE team were asked to investigate the various providers’ referral criteria and liaise with local GPs for further consultation. November Update: LT requested clarity on what the desired output for this work was as there had been previous discussion as to whether a full pathway or list of appropriate tests with where and when they should be carried out would be most beneficial. Dr. Megan John offered to liaise with Dr Lalitha Iyer with a view to obtaining clinical consensus around one coherent joined up pathway. The Committee agreed that this would be useful as clinical consensus would be the key if a joint policy was to be agreed across the region. February 2017 Update: On going. Action: Dr John to develop a draft patient pathway for consideration at the March meeting.

5.2	<p>Minutes of the Priorities Committee held in July 2016 – Action 11.3 – TVPC Meeting dates – It was agreed that for 2017/18 meetings will be held in Berkshire East. CE team to identify a suitable venue.</p> <p>February 2017 Update: Tentative booking for Dedworth Medical Centre, Vale Road, Windsor however parking is an issue. Brants Bridge, Bracknell was suggested as an alternative venue.</p> <p>Action: CE team to explore this alternative option.</p>
5.4	<p>Minutes of the Priorities Committee held in September 2016 – Action 7.5 – Primary hip and knee replacement revision surgery:</p> <p>November action: CE team to seek clarification from NHS England specialised commissioning team for definitions used and their commissioning responsibility.</p> <p>February 2017 Update:</p> <p>a) CE team advised Conversions are a sub category of revisions.</p> <p>b) The local policy was based on NHS England Service Specification stating that all revision surgery is Specialised Commissioning, however there are also NHS England ‘Identification Rules’ which identifies that only third revision and beyond is commissioned by NHS England. Buckinghamshire CCGs have had a confirmation from NHS England recently that definition set i.e. third revision and upwards is specialist and everything else remains non-specialist and continues to be commissioned by CCGs. The TVPC local policy currently does not make allowance for non-specialised providers to do any revision surgery which can have an impact to local skill sets and has the potential to increase specialist centre waiting lists.</p> <p>The Committee agreed the current TVPC Policy will need to be adjusted to reflect the confirmed definition. The revised policy needs to be very clear and specific as per NHS England definition.</p> <p>ACTION 5.4.1: PM to share the email definition received from NHS England and to include reference to the rules.</p> <p>The Committee discussed the potential confusion regarding procedures and revisions. A third procedure would be second revision; a first revision is a second procedure on that joint. The Policy needs to be very clear on what is endorsed; some clinical consultation is required before the Committee can make a decision.</p> <p>The Committee agreed that as an interim the current TVPC policy is to be amended to state that the first revision (second procedure) can be done locally.</p> <p>ACTION 5.4.2: CE team to amend the current policy to reflect the agreed interim change.</p> <p>ACTION 5.4.3: Local CCG Medical Directors to discuss with their orthopaedic leads and provide an outline pathway for review by the Committee at the March meeting.</p>
5.5	<p>Minutes of the Priorities Committee held in November 2016 – Action 6.6 - Paper 16-082 Policy Review: Insulin pumps. The Clinical Effectiveness team to draft a policy document based on TA151 with the addition of gastroparesis and IHA in line with NG17.</p> <p>February Update: CE team have drafted a policy document but have not circulated for comment as it includes reference to Continuous Glucose Monitoring (CGM) which is to be discussed as a separate paper by the Committee.</p> <p>ACTION: Following Committee discussion of the CGM paper the Clinical Effectiveness team to circulate the draft policy for comment. Comments to be returned within 2 weeks following issue.</p>

5.6	<p>Minutes of the Priorities Committee held in November 2016 – Action 7.8 - Paper 16-083 Evidence Review: Freestyle Libre & other Continuous Blood Glucose Monitoring systems for adults with diabetes:</p> <p>February 2017 Update: For review under Agenda item 10. Discussion subsequently postponed due to time constraints.</p>
5.7	<p>Minutes of the Priorities Committee held in November 2016 – Action 8.4 - Paper 16-084 – Evidence Review: Sequential use of Biologics for Rheumatoid Arthritis (RA).</p> <p>The Clinical Effectiveness team were actioned to draft a policy document and circulate for comment, however new evidence has subsequently been published and was brought to the Committee’s attention to discuss whether further review may be necessary in light of this.</p> <p>February 2017 Update: An RCT has recently been published which looks at switching from one anti-TNF to another anti-TNF in RA patients. This study was powered to demonstrate superiority of certolizumab to adalimumab. The results failed to confirm this but suggest that after switching from one anti-TNF to the other patients continued to experience benefits from treatment. The limitations to the findings are that they are specific to switching between certolizumab and adalimumab and not necessarily applicable to switching between other anti-TNF agents. The Committee considered that in view of the new information further discussion around the effectiveness of switching between anti-TNFs should take place before the policy is recommended.</p> <p>ACTION: The Clinical Effectiveness team to schedule a further review and discussion of biologics in RA at the March TVPC meeting.</p>
5.8	<p>Minutes of the Priorities Committee held in November 2016 – Action 10.1 – Surgery for painful big toe: Bunions. Berkshire East CCGs rejected the policy proposals as they did not feel conservative treatment for three months was long enough. CE team to clarify and discuss with Berkshire East.</p> <p>ACTION: Complete</p>
6.0	<p>Paper 16-087 – Evidence Review: MRI Scan – Open/Standing</p>
6.1	<p>Thames Valley CCGs have requested a review of open and standing / upright Magnetic Resonance Imaging (MRI) scans. There has been a number of Individual Funding Requests (IFR) for such scans. In addition whilst Thames Valley CCGs do not have any policies relating to open and standing MRI scans a number of CCGs nationally have adopted a policy.</p>
6.2	<p>The majority of MRI scanners installed in the NHS for general diagnostic purposes employ superconducting magnets with cylindrical bores and produce static fields of magnetic flux density 1.5T. Open MRI systems may offer patients an easier access. Such systems are open on 3 sides. For technical reasons these systems currently use lower static fields of typically 0.2-1.2T. The literature refers to short bore scanners. There does not seem to be a set definition of what a short bore may be.</p>
6.3	<p>Upright, standing or positional MRI (uMRI) is a type of vertically open MRI. Such systems are open at the front and top. A proposed advantage of uMRI is the ability to scan the spine (or joints) in different positions including the position where clinical symptoms are more pronounced.</p>
6.4	<p>Of the CCGs nationally who have adopted policies some state:-</p> <ul style="list-style-type: none"> • An open MRI scan will be funded if the patient is claustrophobic and has not had a successful conventional MRI scan despite the use of an oral sedative. • A patient’s weight or size prevents the use of a standard enclosed MRI scanner. • An upright MRI scan will be funded when a patient is unable to lie properly in a conventional MRI scanner due to severe pain and there is a clear diagnostic need consistent with supported clinical pathways. • Upright MRI scanning will not be funded.

6.5	An assessment by the Washington Health Technology (2007) on the effectiveness of upright MRI (uMRI) for evaluation of patients with suspected spinal or extra-spinal joint dysfunction found no studies which assessed the validity (diagnostic accuracy) of uMRI. The report concluded that without a reasonably solid estimate of diagnostic accuracy, meaningful evaluation of the diagnostic and therapeutic impact of uMRI for various conditions or disease states may not be feasible.
6.6	The randomised controlled trial (RCT) and observational studies that compared open MRI scanners with conventional and short bore MRI scanners were generally found to be of poor quality with small numbers. The RCT found that patients undergoing imaging in an open scanner also suffered with claustrophobic events with differences between the two groups being insignificant. It was found that scans using an open MRI scanner potentially took longer. The RCT and observational studies comparing images from conventional scanners with images from upright scanners were also of poor quality and small patient numbers.
6.7	There have been approximately 75 identified applications for open or standing MRI scans through the IFR process across the Thames Valley CCGs from 1 st April 2015. Reasons include claustrophobia. It is likely that this is an underestimate of actual activity as some will not have gone through the IFR process. There is no actual activity data or costs as there appears to be no codes specific to open or upright MRI scans. It was recently established that the Circle Reading hospital has been absorbing costs for open or upright standing MRIs when they onward refer. The IFR service for Thames Valley CCGs excluding Oxfordshire report that in terms of Berkshire West CCGs there have been 50 applications from the Circle Reading hospital for funding via IFR. Many have been declined. The IFR service reports that invoices received for open or upright / standing scans range from £350 to £500 per scan. It is not known of any local NHS trusts that have an operational open or upright / standing MRI scanner.
6.8	For larger patients the Royal Berkshire Hospital (RBH) have a wide bore scanner and other trusts are likely to buy these wider scanners when buying new equipment in the future. The RBH report that the weight limit allowed on the scanning table is 250kg.
6.10	<p>The attending radiographer advised that the RBH are able to use a number of techniques for patients with claustrophobia:</p> <ul style="list-style-type: none"> • face mask • mirrors to be able to see out of the scanner • if unable to proceed it is suggested that the patient goes back to the GP or person who has referred for the scan and requests oral sedation. • patients returning from their GP with light sedation are more often than not able to achieve a successful MRI scan. It is rarely that the patient is unable to proceed. <p>Rarely an MRI scan with general anaesthetic may be required.</p>
6.12	<p>The Committee agreed that a Thames Valley wide policy would be helpful for commissioning open and standing (upright) MRI scans. The policy should state that open MRI scans will only be funded:</p> <ul style="list-style-type: none"> • in claustrophobic patients who have previously failed an MRI scan in a wide bore scanner with oral sedation at a neighbouring NHS trust. • in obese patients who have tried and previously failed an MRI scan in a wide bore scanner at a neighbouring NHS trust. <p>Standing or upright MRI scans will not normally be funded.</p> <p>Scans undertaken by a private provider will only be funded if the cost is no more than the NHS national tariff.</p>

6.12 Cont..	<p>There was discussion that the policy may include a list of locations with wide bore MRI scanners.</p> <p>ACTION: The Clinical Effectiveness team are to draft a policy document and circulate for comment. Comments are to be received within the 2 week feedback period following issue.</p>
7.0	Paper 16-088 – Policy Update: Low back pain
7.1	<p>In view of the publication of a new NICE guideline NG59 (November 2016) ‘Low back pain and sciatica in over 16s: assessment and management’ the Thames Valley CCGs have requested a review and update of the current local back pain management policies. NG59 replaces Clinical Guideline 88 (May 2009) Low back pain in adults: early management (pain lasting over 6 weeks but less than 12 months). There are currently five joint policies within the Thames Valley CCGs relating to low back pain.</p> <p>It was noted that NICE guidance refers to low back pain only, i.e lumbar back pain. NICE guidance uses the term 'low back pain' which includes any non-specific low back pain which is not due to cancer, fracture, infection or an inflammatory disease process.</p>
7.2	<p>Each of the NICE CG59 recommendations was discussed in relation to current local policies and in relation to changes from the previous NICE recommendations. Input was invited from the attending clinicians for each point. Attending clinicians noted the following general points.</p> <p>Local policy should aim to differentiate between non-specific and specific back pain. Those people with specific back pain which can be identified by a scan or investigation which indicates a pain generator and which responds to injection which is reversible can offer support for care planning and decision whether proceeding with surgical intervention would be appropriate. The NICE guidelines blur between the terms non-specific and specific low back pain.</p> <p>One area for clarification is a nerve route block as a diagnostic test; the attending specialist suggested that a clinical example could be a patient with anterior thigh pain, when they have had a hip replacement and there is a difficulty in differentiating if the pain is arising from the hip replacement or the MRI proven L3 nerve route stenosis; in that situation you may want to do a diagnostic L3 nerve route block to see whether it takes away the thigh pain. It was suggested that there is a gap for this type of scenarios. The number of these patients, however, is small.</p>
7.3	<p>Acupuncture and Manual therapies NICE NG59 recommendation:</p> <ul style="list-style-type: none"> • Do not offer acupuncture for managing low back pain with or without sciatica. • Consider manual therapy (spinal manipulation, mobilisation or soft tissue techniques such as massage) for managing low back pain with or without sciatica, but only as part of a treatment package including exercise, with or without psychological therapy.
7.4	<p>Spinal Injections The new NICE NG59 guideline recommendation is not to offer spinal injections for managing low back pain.</p> <p>The attending clinician noted that there is a role for a limited diagnostic injection in terms of guiding low back pain management. The vast majority of spinal injections are for patients who have facet joint arthritis, where you have a specific area of change in the back that doesn't fit into the non-specific category and injections could be used to treat the back symptoms and also as diagnostic criteria to show where the pain is originating. Again there is a difference between non-specific and specific back pain.</p>

7.4	<p>Epidural injections for sciatica</p> <p>Local data indicates that epidural injections are the biggest field of activity and spend across TV. NICE NG59 guideline recommends:</p> <ul style="list-style-type: none"> • Consider epidural injections of local anaesthetic and steroid in people with acute and severe sciatica. • Do not use epidural injections for neurogenic claudication in people who have central spinal canal stenosis <p>The attending clinician noted that NICE recommendation advises against using epidural injections in patient with stenosis and claudicant leg pain. The clinical experience is that this does represent a useful treatment modality particularly and avoids surgical management in some patients and that there is evidence to support this in the treatment of spinal stenosis.</p>
7.5	<p>Radiofrequency denervation for chronic low back pain</p> <p>Currently there is no local policy across the Thames Valley CCGs for radiofrequency denervation. NICE NG59 recommendations:</p> <ul style="list-style-type: none"> • Consider referral for assessment for radiofrequency denervation for people with chronic low back pain when: <ul style="list-style-type: none"> ○ Non-surgical treatment has not worked for them and ○ The main source of pain is thought to come from structures supplied by the medial branch nerve and ○ They have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale or equivalent) at the time of referral.
7.6	<p>Spinal surgery</p> <p>The current TVPC28 for spinal surgery for the treatment of chronic non-specific low back pain states that surgery is not normally funded for this indication.</p> <p>Spinal fusion; NICE NG59 recommendation is now:</p> <ul style="list-style-type: none"> • Do not offer spinal fusion for people with low back pain unless as part of a randomised controlled trial <p>The attending clinician noted that the recommendation does not clearly state that this is for patients with non-specific low back pain i.e. those patients where a cause has not been identified by the surgeon / clinician. Other conditions which do not fit into the non-specific back pain umbrella should also include spondylolisthesis, spondyloarthropathy and coronal and sagittal plane deformity where surgery may be considered.</p>
7.7	<p>Spinal decompression for sciatica; NICE 59 recommendation:</p> <ul style="list-style-type: none"> • Consider spinal decompression for people with sciatica when non-surgical treatment has not improved pain or function and their radiological findings are consistent with sciatic symptoms. <p>Clinical view was that spinal decompression and discectomy are probably two of the most common operations that we do in clinical practice with very good results. These are usually patients who have had sciatica for beyond 6 weeks, failed conservative management or with spinal stenosis (pain when they walk), conditions that we've tried to manage with injections which have failed so have gone on to decompression surgery.</p>
7.8	<p>Disc replacement; NICE NG59 recommendation:</p> <ul style="list-style-type: none"> • Do not offer disc replacement in people with low back pain with or without sciatica. <p>The attending clinician suggested that there is good evidence for disc replacement. The reason a lot of surgeons have moved away from it is because the revision surgery is complex and carries significant risks, thus only a small number of surgeons are still carrying out this procedure.</p>
7.9	<p>The Committee considered the guidance and the input from the clinicians. It was agreed that clarity of wording is important in differentiating specific and non-specific low back pain. It was also acknowledged that for consistency and coherence we need to be clear if and why the CCGs and providers should choose to deviate from NICE recommendations.</p>

7.9 Cont..	<p>The NICE full guideline evidence for disc replacement notes that the NICE reviewed studies are low or very low in quality. The Committee agreed that the current policies need to be replaced and aligned with the new NICE guideline. Regarding the evidence published since NICE CG59 and the evidence referred by the clinician in support of epidural injections for caludicant leg pain with spinal stenosis; the systematic review in question aimed to review effectiveness of different injectates for epidural injections rather than specific indications and included only small number of studies with spinal stenosis patients. The body of evidence published since NICE for the main indications discussed is not substantial enough to overturn NICE recommendations.</p> <p>The impact of policy changes was discussed. NICE assessment proposes that no resource impact is anticipated from the new guideline. Manual therapy and acupuncture is currently only supported as part of usual NHS care package. Aligning with NICE CG will not have significant impact, however, provision of acupuncture will no longer be supported. For epidural injections and therapeutic facet joint injections aligning with NICE CG does not represent a change in practice. Stating that other spinal injections are not normally funded may offer some savings. Introducing facet joint denervation as an option for chronic low back pain will be a new policy statement where activity may increase. For spinal surgery there would be no significant changes to current local policy or practice, clarification will be made which surgical procedures will not be recommended.</p> <p>It was noted that NICE guidance does not make recommendations around neck pain. The Committee agreed to retain the neck pain element of the current policy on diagnostic and therapeutic facet joint injections (not normally funded).</p> <p>ACTION: Clinical Effectiveness team to draft a policy document and circulate for comment. Comments are to be received within the 2 week feedback period following issue.</p>
8.0	Paper 16-089 - Evidence Review: Radiofrequency denervation of sacroiliac joint
8.1	<p>The Thames Valley CCGs have requested a review of the evidence for using radiofrequency denervation for low back pain originating from the sacroiliac (SI) joint. There have been a number of individual funding requests in 2015-16 and to date for this treatment and all have been approved. The recently published NICE guideline CG59 (November 2016) Low back pain and sciatica in over 16s: assessment and management did not include sacroiliac joint pain in their scope. There are currently no local policies relating to sacroiliac joint interventions with the Thames Valley CCGs.</p>
8.2	<p>The contribution of the SI joint to low back and lower extremity pain has been a subject of debate; it is generally accepted that approximately 10% to 25% of patients with persistent low back pain may have pain arising from the SI joints. In spite of this, there are currently no definite conservative, interventional, or surgical management options for managing this dysfunction.</p>
8.3	<p>Overall the evidence for the use of radiofrequency denervation for SI joint pain is limited in quality and in quantity. Generally the studies have been on small patient populations and limited to maximum 12 month in follow-up. Uncertainties associated with the radiofrequency denervation that remain include; the effectiveness, number and approach of the necessary diagnostic blocs required to diagnose SI joint pain accurately, duration of the pain relief following denervation and the rate of nerve regeneration and the potential need for repeat interventions and overall safety of the procedure. The attending clinician agreed with the review summary.</p>

8.4	<p>The Committee agreed to recommend a statement as part of the low back pain policy that SI joint denervation is not normally funded.</p> <p>ACTION: Clinical Effectiveness team to include SI denervation recommendation in the low back pain policy under development.</p>
9.0	Paper 16-090 – Evidence Review: Use of melatonin in children to improve sleep and subsequent behaviour
9.1	The Thames Valley CCGs have requested a review of the use of melatonin in children to improve sleep. There are currently no related policies within Thames Valley CCGs, although CCGs have prescribing and shared care protocols in place.
9.2	<p>Melatonin is used for treating sleep onset insomnia and delayed sleep phase syndrome in children with conditions such as visual impairment, cerebral palsy, intractable epilepsy, neurodevelopmental disabilities attention deficit hyperactivity disorder, autism, learning difficulties and chronic fatigue syndrome. It is also sometimes used before EEG investigations.</p> <p>The Committee heard from local specialists and acknowledged the distressing effects sleep disorders can have on children's behaviour and development as well as the families' quality of life.</p>
9.3	The first-line treatment for children with sleep problems is good sleep hygiene and behavioural therapy and that should be core to any treatment. There are alternative medications to melatonin that can be used but all of them are off label. No preparations of Melatonin are currently licensed for use in children. There is only one licensed form available in the UK, which is licensed for adults aged 55 and over. The MHRA suggest that they would prefer, if using off label, use of the licensed form off label rather than using the solutions which are available as 'specials' and are unlicensed products.
9.4	<p>There are a number of related national guidelines which make recommendations around sleep disorders and melatonin use in children:</p> <ul style="list-style-type: none"> • NICE CG137 (2016): for epilepsy - indicates that in children and young people, a sleep EEG is best achieved through sleep deprivation of the use of melatonin. • NICE NG11 (2015): challenging behaviour and learning disabilities - which supports the use of melatonin when behaviour interventions have been tried and after consultation with a psychiatrist and experts; regular reviews are also recommended. NICE state that melatonin is likely to be cost effective in the management of sleep problems in children and young people with disabilities. • NICE CG170 (2013): Autism – makes recommendations on sleep disorder treatment and pharmacological management but does not make specific recommendations on use of Melatonin. • NICE CG53 (2007): Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) recommends melatonin may be considered • SIGN guidance for autism recommends that melatonin should be an option.
9.5	The Committee discussed the costs of melatonin in primary care; the oral solution costs between £70 to £200 (special medicines), the Circadin preparation costs approximately £15 per 30 tablets. Buckinghamshire CCG and Berkshire East CCG federations have spent approximately £95,000 on melatonin in 2016/17. Oxfordshire CCG spend was £64,000. It is not possible from prescribing data to establish patient numbers or costs per indication.
9.6	The Committee discussed the evidence for melatonin. Two systematic reviews/meta-analysis were identified which assessed melatonin use in primary insomnia, however both were found to be non-systematic in the identification of studies and whilst the meta-analysis included studies of higher quality the majority of included studies were conducted more than 10 years ago. These reviews suggest melatonin decreases sleep onset latency, increases total sleep time and improves overall sleep quality. The effects of melatonin are generally modest but do not appear to dissipate

9.6 Cont..	with continued melatonin use. One RCT reviewed the longer term use of melatonin over a period of time and concluded that it remains effective over time. The meta-analysis on delayed sleep phase disorder found that total sleep time in the children sub group increased by 28.39 minutes, however, it is not clear whether this is clinically significant.
9.7	The attending clinician confirmed that behaviour solutions are offered first before melatonin is prescribed; melatonin is not used as a first-line treatment. She emphasised the impact of sleep disorders on families and described a local case report. The local specialist confirmed that she agreed with option 2, that melatonin should be offered in line with NICE guidance in children with neurodevelopmental disorders. She felt melatonin is very beneficial in children with learning disabilities including autism, ADHD, and all of the significant developmental difficulties.
9.8	<p>The Committee considered the other feedback submitted by local clinicians. A specialist from Oxford University Hospitals suggested an option for melatonin to be initiated in secondary care for children who have persistent sleep onset insomnia, difficulty waking in the morning and not responding to sleep hygiene advice.</p> <p>The Committee agreed the evidence for melatonin in primary sleep disorders was not strong enough to support use for this indication.</p> <p>The Committee also discussed melatonin use in children who are blind. No specific evidence was identified relating to children who are blind, but the Committee noted that this may be an area for further consideration in future.</p> <p>It was noted that prescribing of melatonin in primary care can only take place where a shared care protocol is in place locally as it must be initiated by a specialist. It was agreed that melatonin should be funded for use in children with neurodevelopmental disorders including autism, ADHD and learning difficulties in children with challenging behaviour. The policy should state that prescribing must be in line with local Medicines Optimisation guidance or protocols.</p> <p>ACTION: Clinical Effectiveness team are to draft a policy document and circulate for comment. Comments are to be received within the 2 week feedback period following issue.</p>
10.	Paper 16-083 – Policy Update: Continuous Glucose Monitoring Systems
10.1	Due to time constraints this topic is deferred to the next meeting.
11.	Any Other Business
11.1	Work Programme for 2017-18. Some in-year requests have been received and are included in the programme however, priorities may need to be adjusted if necessary.
11.2	<p>Terms of Reference and Ethical Framework –these documents are due for annual review therefore representatives were asked to review and bring their comments and/or points to consider to the May meeting.</p> <p>A point was raised in reference to the definition of ‘exceptionality’, which has arisen as part of an ‘Independent Review of the Individual Patient Funding Request Process’ in Wales. It was suggested that a new focus may be considered around the definition; ‘Whether a patient is given an intervention should depend on whether the patient will gain significant clinical benefit from the intervention, and whether the intervention offers reasonable value for money’. To be discussed further as part of the review of the Committee documents.</p>
12.	Next meeting
	The next meeting will be Wednesday 22nd March 2017, to be held in Conference Room A, Jubilee House, Oxford, OX4 2LH.
13.	Meeting Close
	The Chair thanked everyone for their contributions to the discussions and closed the meeting.