Berkshire West Clinical Commissioning Group
Buckinghamshire Clinical Commissioning Group
East Berkshire Clinical Commissioning Group
Oxfordshire Clinical Commissioning Group

Thames Valley Priorities Committee

Minutes of the meeting held Wednesday 27th March 2019

Room G29/G30, 57-59 Bath Road, Reading RG30 2BA

Alan Penn	Lay Member Chair	Thames Valley Priorities Committee
Sarah Annetts	IFR Manager (Clinical)	SCW CSU
Jane Butterworth	Associate Director Medicines Optimisation	Buckinghamshire CCG
Linda Collins	Clinical Effectiveness Manager (CCG)	Oxfordshire CCG
Edward Haxton	Deputy Finance Director	Berkshire West CCG
Dr Megan John	GP, Berkshire East CCG Lead	East Berkshire CCG
Catriona Khetyar	Head of Medicines Optimisation	East Berkshire CCG
Ravi Lukha	Public Health Specialist Registrar	Public Health Services for Berkshire
Robert Majilton	Deputy Chief Officer	Buckinghamshire CCG
Marion Mason	Assistant IFR Manager	SCW CSU
Prof. Chris Newdick	Professor of Health Law	University of Reading
Dr Raju Reddy	Secondary Care Consultant	Berkshire West CCG
Amaka Scott	Commissioning Interfacing Pharmacist	Berkshire West CCG
Dr Karen West	Clinical Director Integration	Buckinghamshire CCG

In Attendance:

Tiina Korhonen	Clinical Effectiveness Lead	SCW
Kathryn Markey	Clinical Effectiveness Manager	SCW
Rebecca Hodge	Clinical Effectiveness Manager	SCW
Gillian Barlow	Clinical Effectiveness Manager	SCW
Katie Newens	Clinical Effectiveness Researcher	SCW
Rachel Finch	Clinical Effectiveness Administrator – Minute Taker	SCW

Topic Specialists in Attendance for Agenda Items:

Item 6 – Evidence Review: Continuous glucose monitoring; paediatrics		
Fiona Regan	Consultant Paediatrician, Paediatric Endocrine Lead,	Wexham Park / Frimley Health NHS Foundation Trust
Fiona Ryan	Consultant in Paediatric Endocrinology and Diabetes, lead for Paediatric Endocrinology and Diabetes,	Oxford University Hospitals NHS Foundation Trust
Joanne Spinks	Consultant Paediatrician Clinical Lead for Paediatric Diabetes	Royal Berkshire Hospital
Jane Haest	Lead Paediatric Diabetes Specialist Nurse	Oxford University Hospitals NHS Foundation Trust

Item 7 – Evidence Review: Management of ear wax		
Alan Bryant	Deputy Head of Audiology	Royal Berkshire NHS Foundation Trust
Elizabeth Anderson	Sister, ENT Outpatients	Royal Berkshire Hospital
Camille Telloren	Senior Staff Nurse, Ear care clinic	Royal Berkshire Hospital
Item 8 – Evidence Review: Lignocaine infusions for chronic pain		
Dr Deepak Ravindran	Consultant in Anaesthesia, Pain and Musculoskeletal Medicine; Clinical Lead for Pain Medicine	Royal Berkshire NHS Foundation Trust
Dr Husham AL-shather	Consultant in Pain Medicine	Royal Berkshire NHS Foundation Trust
Kayleigh Sloman	Nurse Lead	Royal Berkshire NHS Foundation Trust

Apologies:

Dr Mark Hancock	Medical Director	Oxford Health NHS Trust
Jo Jefferies	Consultant in Public Health	Bracknell Forest
Prof. Meghana Pandit	Medical Director	Oxford University Hospital NHS Trust
Dr Jacky Payne	GP	Berkshire West CCG
Sarah Robson	Head of IFR	SCW
John Seymour	Chief of Staff Medicine, Frimley Health	East Berkshire CCG
Dr Mark Sheehan	Special Advisor – Ethics	University of Oxford
Fiona Slevin-Brown	Director of Strategy and Operations	East Berkshire CCG
Graham Smith	Lay member	Buckinghamshire

1.	**Welcome & Introductions**
1.1	The Chair opened the meeting and welcomed the members of the Committee.
2.	**Apologies for Absence**
2.1	Apologies recorded as above. The Chair informed the Committee that Dr Graham Jackson, Buckinghamshire ICS Clinical Lead had left the Committee. The Committee expressed their thanks for the valuable service Graham has provided over the years. The Committee welcomed Dr Karen West, Clinical Director Integration Buckinghamshire as Graham's replacement.
2.2	The meeting of 28th November 2018 and 23rd January 2019 were not quorate. **March 2019 update:** Both sets of minutes and recommendations have been retrospectively accepted by non-attending members of the Committee. Ravi Lukha, Public Health Speciality Registrar Berkshire will represent Public Health at this and future Committee meetings.
3.0	**Declarations of Interest**
3.1	Nothing declared.
4.	**Draft Minutes of the Priorities Committee meeting held 23rd January 2019 - Confirm Accuracy**
4.1	The draft minutes were accepted as a true record of the meeting.
5.	**Draft Minutes of the Priorities Committee meetings – Matters Arising**
5.1	**Minutes of the Priorities Committee held in July 2018 – Action 6.6.2 - Paper 18-006 – Evidence Review: Sequential use and dose escalation of biologics in Crohn's disease** Attending specialist clinicians agreed to develop a policy and pathway for the sequential use of biologics in Crohn's disease with their colleagues from Oxford, Reading, Buckinghamshire and Frimley. The Committee suggested this may be presented to the 26th September TVPC meeting. **September 2018 Update:** Specialist clinician is meeting with colleagues in early October to commence the policy and pathway development process. Committee to be updated at 28th November meeting. **November 2018 Update:** Clinical Effectiveness team to contact specialist clinician for a date when the policy and pathway can be presented to the Committee.

5.1 cont.	**January 2019 Update:** The clinicians are still committed to preparing a pathway to present to the Committee however no information has been received from them yet. The Clinical Effectiveness team to ask the clinicians to bring their pathway to the next meeting, 27th March. Lindsey Barker agreed to follow up with RBH. Should clinicians be unable to provide information for the next meeting the Clinical Effectiveness team propose looking at the Buckinghamshire and Berkshire West policy's with a view to developing an agreement. **March 2019 Update: Clinicians have indicated a pathway will be brought to 22nd May meeting.**
5.2	**Minutes of the Priorities Committee held in November 2018 – Action 6.1 – HealthWatch representation - January 2019 Update:** Healthwatch responded to a letter sent to them by the Chair confirming they will not attend the Committee as voting members. Dr Graham Jackson to progress with seeking non-executive lay representation. **ACTION Complete**
5.3	**Minutes of the Priorities Committee held in January 2019 – Action 6.5 - Paper 18-027 – Matters Arising: Negative Pressure Wound Therapy – Update** The Clinical Effectiveness team to draft a policy recommendation: Topical negative pressure for wound therapy (NPWT); vacuum – assisted wound closure dressings and circulate for comment. Comments to be received within the 2 week feedback period following issue. **ACTION Complete**
5.4	**Minutes of the Priorities Committee held in January 2019 – Action 7.4 - Paper 18-028 – Evidence Review: Clinical threshold for access to audiology services** The Clinical Effectiveness team to draft a policy recommendation for adults with mild hearing loss and circulate for comment. Comments to be received within the 2 week feedback period following issue. **ACTION Complete**
5.6	**Minutes of the Priorities Committee held in January 2019 – Action 8.3 - Paper 18-029 – Policy Update: Anti-VEGF treatments and dexamethasone implants for macular oedema caused by central and branch retinal vein occlusion** Jane Butterworth to send the results of the Bucks CCG audit to the CE team who will circulate to the Committee for information. **ACTION Complete**
5.7	**Minutes of the Priorities Committee held in January 2019 – Action 8.4 - Paper 18-029 – Policy Update: Anti-VEGF treatments and dexamethasone implants for macular oedema caused by central and branch retinal vein occlusion** The Clinical Effectiveness team to draft an updated recommendation to policy TVPC 5: Anti-VEGF treatments and dexamethasone implants for macular oedema caused by central and branch retinal vein occlusion and circulate for comment. Comments to be received within the 2 week feedback period following issue. **ACTION Complete**
5.8	**Minutes of the Priorities Committee held in January 2019 – Action 9.3 - Paper 18-030 – Primary hip and knee joint replacement revision surgery – proposed thresholds** The Clinical Effectiveness team to circulate the draft update to policy recommendation TVPC55: Primary hip and knee replacement revision surgery for comment as minuted. Comments to be received within the 2 week feedback period following issue. **ACTION Complete**
5.9	**Minutes of the Priorities Committee held in January 2019 – Action 10.3 - Paper 18-031 – Current Policy Updates** The Clinical Effectiveness team to draft the updated policies as discussed and circulate for comment. The Clinical Effectiveness team to withdraw TVPC26. Comments to be received within the 2 week feedback period following issue. **ACTION Complete**
5.10	**Minutes of the Priorities Committee held in January 2019 – Action 11.1 - Paper 18-032 – NHSE Evidence based interventions (EBI) – Update** The Clinical Effectiveness team to schedule policies for chalazia and tonsillectomy for early review and adoption. **March 2019 Update:** Proposed for discussion at May/July 2019 Committee meeting.

5.11	**Minutes of the Priorities Committee held in January 2019 – Action 13.1 – Any Other Business – Public Health representation at Case Review Committee** 1. The Public Health (PH) representative from East Berkshire sent a query to the Committee regarding PH representation on the Individual Funding Request (IFR) 'case review committees'. **March 2019 Update:** This item sits outside of the Priorities Committee as it relates to IFR case review committees. Ravi Lukha, PH representative and East Berkshire have since been in discussion regarding the matter. **ACTION Complete** 2. A question was also put to the Committee regarding what equity audits have been carried out about the impacts of our policy recommendations, and whether socio economic status and ethnicity are audited. Due to lack of time at the Committee, it was agreed that this will be discussed at the next meeting matter arising. **March 2019 Update: East Berkshire PH representative raised the thought that people who were higher educated, had access to more information were more likely to appeal a policy successfully and wanted to know if that explored as part of IFR outcomes.** The Committee acknowledged that considering social determinants of health are important and that health equity is spread unevenly across the echelons of society. Whilst not directly concerned with particular recommendations this Committee makes, it would be diligent to explore if there may be need to reconsider how we word some of our policies, it may influence the way some CCGs commissions support for patients and customers or even how we present our policy websites. The Committee agreed that GP practice demographics data would allow a review of the IFR applications/appeals processed against the outcomes and demographics data. **ACTION: CCGs to discuss and work with the Head of IFR as to the best method of extracting a report(s) by GP practice over at least two financial years for socio economic status and ethnicity analysis. Review report to be discussed at the Committee Workshop topic scoring event to be held in November 2019.**
6.	**Paper 18-034 – Evidence Review: Continuous glucose monitoring; paediatrics**
6.1	Thames Valley Clinical Commissioning Groups (CCGs) requested a review of continuous glucose monitoring (CGM) in paediatric patients in order to establish the clinical and cost effectiveness of using CGM in type 1 diabetics and to agree a common policy across the Thames Valley that sets clear thresholds and ensures access to CGM for appropriate paediatric patients, children and adolescents. NHS England is proposing that CGM and the related consumables are removed from national tariff. These will be added to the list of high cost drugs and devices for 2019-2020.
6.2	NICE guideline NG18 Diabetes (type 1 and type 2) in children and young people: diagnosis and management recommends offering on-going real-time CGM with alarms to children and young people with type 1 diabetes who have: frequent severe hypoglycaemia or impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety) or inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities). The guideline also says to consider ongoing real-time CGM for neonates, infants and pre-school children; children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level); children and young people who have comorbidities (for example anorexia nervosa) or who are receiving treatments (for example corticosteroids) that can make blood glucose control difficult. Guidance from the Association of Children's Diabetes Clinicians (2018) supports NICE guidelines. It does not recommend CGM in patients with an HbA1c>10%. The guidance also recommends criteria for withdrawal.
6.3	In recent years technology has advanced quicker than the evidence from research trials. The benefits of support to the parent and patient and the more advanced functions of CGM that may optimise therapy are not well documented in the published studies. A Health Technology Assessment (HTA) dated 2018 suggested that CGM is more effective than self-monitoring of blood

6.3 cont.	glucose for some outcomes, such as time spent in target glucose range and time spent outside the target glucose range. Similar findings for severe hypoglycaemic events were found. A further HTA concluded that an integrated pump and CGM with low glucose suspend (LGS) function reduces hypoglycaemic events more than any other treatments. Evidence did suggest that parental fear of hypoglycaemia is reduced with the use of CGM.
6.4	Across the Thames Valley, 62 IFRs for CGM have been approved since April 2016. This is unlikely to be the total number of patients using CGM. The National Paediatric Diabetes Audit (NPDA) records that 66 patients were using NHS funded CGM across Thames Valley providers as at 31st March 2018. The number of patients using CGM has since increased. Currently (March 2019) there are 131 patients across Thames valley providers using NHS funded CGM who fulfil the NICE criteria. Local consultants suggest an additional 90 patients per year every year may require CGM. The cost of CGM per annum is approximately £2000-£3500 dependant on the device. There were 68 hypoglycaemic non-elective admissions for patients 0-18 years with a diagnosis of Type 1 diabetes across Thames valley CCGs since April 2015. There were 5 hyperglycaemic non-elective admissions for patients 0-18 years with a diagnosis of Type 1 diabetes across Thames Valley CCGs since April 2015. The cost of CGM may be offset by the reduced self-monitoring of blood glucose for example the Dexcom G6 CGM system does not require calibration or additional capillary glucose measurements. CGM use may also reduce unplanned admissions for hypoglycaemic and hyperglycaemic episodes.
6.5	The Specialists in attendance made the following points: • The Dexcom G6 CGM system is currently the most accurate standalone CGM system, and does not require finger prick blood glucose testing. It is not able to communicate with an insulin pump. Glucose trends can be followed on a compatible mobile phone. It has an alarm and can predict high and low glucose levels, which is reassuring for parents. • The device has to be used properly and its use is stopped if patients are not using it correctly. There are withdrawal criteria in the ACDC guidelines. • CGM can reduce the risk of complications from diabetes and has a huge impact on patients' lives. • Not all admissions for hypoglycaemia will be eliminated. • For very young children using an insulin pump, a CGM system that is compatible with an insulin pump suspends the delivery of insulin and may prevent unplanned admissions for hypoglycaemic events. • Technology is evolving into closed loops systems, whereby the CGM reading is informing the pump whether to suspend insulin or give more insulin. It is likely within the next decade that most patients will be using a closed loop system. • Pre-school aged children are very difficult to control as they have erratic eating and exercise habits. Without CGM it is extremely difficult to control their blood glucose. All pre-school age children under the age of 5 should be offered CGM. Patients, who have had an unexplained hypoglycaemic seizure without an obvious identifiable cause, should also be offered CGM. • The use of CGM may reduce the need for an insulin pump. • The risk of complications is that much greater in a patient who is diagnosed at a young age. It is even more important to keep these patients healthy as they may have had diabetes for 15 years before they transition into the adult service. These patients may start getting complications in their 20s.

6.6	The Committee considered the Association of Children's Diabetes Clinicians (ACDC) (2018) withdrawal criteria and agreed the Clinical Effectiveness team will draft a policy recommendation for CGM to include the following threshold criteria: • Patients meeting the criteria within the NICE guidelines will be offered CGM. • Children who have had one episode of severe hypoglycaemia (requiring 3rd party assistance) without an obvious identifiable cause will be offered CGM. • CGM will be offered to children younger than 5 years as a routine standard of care. • Self-funding patients who have met the NICE guideline criteria at the onset of their self-funding will be offered NHS funded CGM. • Withdrawal criteria will be specified in line with ACDC guidelines. • Patients will be reviewed at the age of 12 years and on transfer to adult services. **ACTION: The Clinical Effectiveness team to seek attending specialist input regarding the ACDC guideline CGM withdrawal criteria to clarify whether all or some of the withdrawal criterion should to be met.** **Post meeting note:** The specialists in attendance have offered the following advice: 1) The withdrawal criteria are '**ors'** not 'ands' and CGM should be withdrawn if one criterion is not met. 2) The 'does not need to be withdrawn criteria' refers to separate patient groups that experience a hypo seizure or younger children. A younger child would be defined as less than 5 years. 3) The consultants have some reservation about withdrawing the CGM if the hypoglycaemia unawareness has not improved. If the patient is still hypo unaware then CGM is still needed. This has come from the ACDC guidelines but perhaps this should be taken this out as it does not make much clinical sense. As agreed with the consultants the policy recommendation has been amended to read 'CGM will be withdrawn if hypo awareness has improved'. 4) 3 months may not be long enough to see measurable improvements in some of the criteria. The consultants would favour reviewing use and indications at 3 months (allows time to re-emphasise criteria/arrange psychology review etc as needed) then withdrawing after 6 months if they have not been met. This is to give time to effect change. The policy recommendation has been edited to reflect the above comments. **ACTION: The Clinical Effectiveness team to draft a policy recommendation: Continuous glucose monitoring (CGM) – paediatrics and circulate for comment. Comments to be received within the 2 week feedback period following issue.**
7.	**Paper 18-035 – Evidence Review: Management of ear wax**

7.1	Thames Valley CCGs requested a review of the management of earwax in adults to address variation in practice. The evidence review sought to answer the following questions:
	• What is the most clinically effective way of clearing ear wax:
	  ○ Where a procedure needs a clear ear canal e.g. for hearing aids to be fitted, thus avoiding cancelled appointments when the procedure cannot be carried out?
	  ○ Where a patient is affected by ear wax but its removal is not critical for an investigation/procedure what is the most cost and clinically effective way of treating?
	• For patients who require hearing aids is there a recommendation that can be made to prophylactically prevent the build-up of earwax?

7.1 Cont.	Impacted earwax is wax that has been compressed in the ear canal, completely obstructing the lumen. There are several methods for removal of impacted earwax: • Ear drops to soften wax and aid removal • Ear irrigation using an electronic irrigator (previously known as syringing). • Manual removal, where earwax is removed by the clinician inserting a curette, forceps or suction tip (microsuction) into the ear, dislodging the wax and retracting it.
7.2	NICE guideline NG98: Hearing loss in adults: assessment and management (2018) recommends: • Offer to remove earwax for adults in primary care or community ear care services if the earwax is contributing to hearing loss or other symptoms, or needs to be removed in order to examine the ear or take an impression of the ear canal. • Consider ear irrigation using an electronic irrigator, microsuction or another method of earwax removal (such as manual removal using a probe) for adults in primary or community ear care services. Recommendations around the clinical setting for the removal of earwax are based on NICE committee consensus. It was acknowledged by the committee that there was delay in management of earwax and over-referral to secondary ENT services. A Draft NICE Quality Standard: Hearing loss (adult onset) due to be published in July 2019 contains a statement that ear wax removal should be removed in primary care or by ear care services. The draft Quality standard notes that this means Commissioners (CCGs and NHSE) should ensure that they commission services with the appropriate equipment, capacity and expertise to carry out earwax removal for adults in primary or community care if their earwax is contributing to hearing loss or other symptoms, or is preventing examination or effective management
7.3	The available literature does not make a distinction in relation to different removal techniques for patients who need a clear ear canal for hearing aids to be fitted or where a patient is affected by ear wax but its removal is not critical for an investigation or a procedure. No evidence was found comparing the clinical effectiveness of irrigation with other mechanical methods. No systematic reviews or randomised controlled trials examining the prophylactic management of earwax were identified. NICE cite that they are aware of the practice of using regular small quantities of olive or almond oil in order to keep earwax soft to try to avoid build-up of earwax. This use of oil was not researched and the NICE committee know of no evidence to advise against this practice if it is found to help the individual. There was insufficient evidence available to identify the most cost-effective method of removing earwax. According to NICE, the cost of the initial purchase of an irrigation machine is around £159 and will be split over many hundreds of uses. Consumables cost £0.54 per use. The major cost involved is the healthcare professional's time. Microsuction machines range from £1,350 if purchased with a loupe to £14,000 if a high end microscope is used. Consumables are slightly under £3 per use. As diagnosis is not well recorded in outpatient data, it was not possible to distinguish activity specifically for impacted earwax in secondary care, which was identified for the following OPCS codes: D07.1 Irrigation of external auditory canal for removal of wax – includes syringing and washout, D07.2 Removal of wax from external auditory canal NEC, D07.8 Other specified clearance of external auditory canal, D07.9 Unspecified clearance of external auditory canal. It may therefore be assumed that a large number of the procedures identified by SCW analytics could be for other diagnoses or complex patients. Overall, however, the activity indicates significant variation across the TVPC CCGs, with 2017/18 activity per 100,000 population as follows: • East Berkshire CCG: 531.7 • Oxfordshire CCG: 666.5 • Berkshire West CCG: 777.9 • Buckinghamshire CCG: 1,061.2

7.4	The Specialists in attendance made the following points: • From an audiology perspective, earwax has always been an issue with hearing aids and historically has been managed by primary care, with complex patients managed by ENT. Only over the last 2 years has earwax removal been a consideration for audiology services. ENT have also seen an increase in patients being referred that don't fit the ENT referral criteria and could be seen in the community. This ties in with why the NICE guidelines have addressed it as there is now a variation in practice in terms of managing wax. • NICE recommendations provide a sensible solution to reduce variability in the area and have a robust and consistent pathway with an understanding of the need to avoid cost pressures. • The specialists recommend that in patients whose wax has cleared easily, the use of olive oil or an alternative drop once a week, one ear at a time at night times should stop impacted earwax reoccurring. However, all patients are different and some people produce a lot of wax or have narrow ear canals where the wax doesn't clear easily. Prophylaxis may not be effective in these patients. Hearing aids are also a hindrance to earwax clearing naturally. Patients with learning disabilities and Down's syndrome may have physiological reasons they need to be referred to ENT.
7.5	The committee discussed the following points: • Any policy should state that earwax removal 'could be' available in primary or community care, rather than should be. • A policy for earwax removal should include 3 groups of patients: 1. those people who do not need the NHS to pay for their earwax to be cleared 2. Those who need to go into secondary care 3. Those for whom self-management has failed and for whom CCGs might commission services, whether it is from an audiology provider or from a GP practice. • Ear drops should not be prescribed on the NHS and patients should be directed to speak to their pharmacist. Following discussion the Committee agreed the Clinical Effectiveness team to draft a policy recommendation for the Management of earwax in adults to include the following: • Self-management, including ear drops as a treatment and prophylaxis, and not inserting cotton buds and hairpins into the ear. • Criteria for patients who may be suitable for earwax removal in primary or community care services. • Criteria for patients who require referral to ENT services for earwax removal **ACTION: The Clinical Effectiveness team to draft a policy recommendation: Management of ear wax and circulate for comment. Comments to be received within the 2 week feedback period following issue.**
8.	**Paper 18-036 – Evidence Review: Lignocaine infusions for chronic pain**
8.1	Thames Valley CCGs requested a review of lidocaine infusions to understand the clinical and cost effectiveness of its use for chronic pain such as fibromyalgia to establish whether the TVPC can recommend a policy for its use. There are a number of individual conditions that can cause chronic pain, this review is limited to 'chronic pain', 'fibromyalgia' and 'neuropathic pain'; it is specific to lignocaine infusions, other treatments for chronic pain are outside of the scope of this review.
8.2	There are no national guidelines regarding lidocaine use for chronic pain. There are NICE, Royal College of Anaesthetists and SIGN guidelines on the assessment and management of chronic pain; however, these do not include lidocaine in their standard pharmacological treatments for chronic pain or fibromyalgia. There is a NICE guideline for Chronic pain: assessment and management in development due for publication in 2020 but it is not yet known whether lidocaine will be included.

8.2 Cont.	The Royal Berkshire NHS Foundation Trust (RBH) and Oxford University Hospitals NHS Trust (OUH) have protocols and pathways for intravenous (IV) lidocaine infusion therapy for specific indications such as neuropathic pain, complex regional pain syndrome, fibromyalgia, chronic widespread pain and for pain that has not responded to any other treatments available. There is wide variation in activity across the TV CCGs, with the highest activity over the last 3 years reported at Berkshire West CCG. Whilst usage of lignocaine infusions is low for the other CCGs, there is a trend towards increasing activity across the CCGs. In 2015-16 there were 276 procedures (£148,556) and in 2017-18, 726 procedures (£396,566) in TV in total. Local activity data is based on the HRG code - Continuous Infusion of Therapeutic Substance for Pain Management, there is no specific code for lidocaine infusion. Data is recorded per procedure and therefore may include multiple procedures per patient. In the RBH lidocaine pathway, there are an average number of 4 lidocaine infusions per course.
8.3	There is a paucity of high quality evidence relating to lidocaine infusions for chronic pain. The review found one systematic review (SR) on phantom limb pain and one randomised controlled trial (RCT) relating to post herpetic neuropathic pain and complex regional pain syndrome and two RCTs for fibromyalgia. For neuropathic pain the SR evidence found there was no difference between lidocaine and placebo for the relief of phantom limb pain. However the RCT evidence did show that IV lidocaine can provide a short term reduction in pain but this was transitory. To note these studies were of small sample sizes and investigated specific neuropathic pain (NeP) conditions and therefore it is not possible to generalise to a wider cohort of patients with NeP. With regard to fibromyalgia, both RCTs combined the use of lidocaine with amitriptyline and reported no modification of pain intensity. In one of the studies there was a lower pain intensity found in a lidocaine group at two weeks but at no other times in the study. The combination of drugs meant pain relief could not be solely attributed to lidocaine, due to an analgesic effect of amitriptyline. Again to note treatment lengths were of short duration (4 weeks) and follow-up was also of short duration therefore the long term effects of lidocaine were not able to be evaluated. Sample sizes were small and of different populations. No conclusions could be drawn with regards to recommended dosages or duration of treatment with lidocaine.
8.4	The Specialists in attendance made the following points: • It was acknowledged that Berkshire West CCG shows the highest activity for lidocaine infusion use. • The Pain Service at Royal Berkshire Hospital (RBH) uses the infusion pathway for patients who have already tried other medication and pain relief interventions with no effect. • There is also a long wait for good quality pain management programmes. • The nurse-led lidocaine infusion pathway was introduced in RBH in April 2018. It is for patients with a diagnosis of fibromyalgia, chronic widespread pain, complex regional pain syndrome or severe chronic migraine headaches. The pathway also includes elements of evidence-based education, patient information and self-management strategies. The patients are assessed for entry criteria for the pathway and followed up at 10 weeks post infusion, at which point patients are assessed for further infusions or are referred back to the pain consultant for alternative pain management programmes. • The infusion treatments are part of a course of 4 treatments, 6 months apart, followed by self-management strategies and psychological counselling on a one to one basis. Patients are discharged back to the GP after 2 years with a personalised pain management plan. The Specialists reported that most patients have 2-3 infusions in total.

8.4 Cont.	• Departmental audits carried out in the last two years reported that patients with fibromyalgia have benefitted most from the infusions. A patient satisfaction review at RBH of 50 people with fibromyalgia between March-November 2018 reported 30 patients (60%) had 50% or more pain reduction, 32 patients (64%) showed improvement in daily activities and 23 patients (46%) said sleep was improved. The pain relief was reported to last for 3 months or more in 28 patients (55%). • Most of the patients at RBH receiving the treatment are from within Berkshire, however a small number of patients attend from Oxford and South Oxfordshire, East Berkshire and Bracknell. • The Specialists noted that there has been a variation in practice from 2010 when 70% of patients seen had low back pain or muscular-skeletal (MSK) conditions. There are some patients with central neuropathic pain, post stroke pain and multiple sclerosis (MS), however up to 32 fibromyalgia patients can be seen per week in 1 consultant clinic. • The clinicians commented that there are other NHS Trusts in the UK that also offer this treatment.
8.5 **16.10**	The Committee made the following points: • It was noted that that the activity was significantly higher in Berkshire West CCG than in the rest of the TV CCGs, not necessary explained by population demographics. There were also differences in clinical view of who should be treated in between local centres. The pain consultants at Oxford do not offer lidocaine therapy for patients with fibromyalgia. • There were concerns regarding the lack of clinical evidence of effect and the placebo effect of lidocaine infusions. The Committee raised the issues of potential significant placebo effect of the treatment involving admission to hospital. There is a lack of good quality evidence that lidocaine infusion works, but there is good evidence for the benefits of counselling and cognitive behavioural therapy (CBT) for patients with chronic pain and the focus of care should be on long term self-management and psychological support in addition to medical therapy. Ravi Lukha left the meeting • Concern was also raised regarding the patient safety; the dosage of lidocaine used was more than the recommended dose for lidocaine by infusion and the potential harm to patients was a significant concern. Local anaesthetic toxicity is well known, potential to cause fits or cardiac arrest. A significant side-effect event would be devastating. • To also note that the use of lidocaine (lidocaine hydrochloride) intravenously for chronic pain is outside of its licenced indications. • The Committee did acknowledge the complexity of chronic pain condition and the real problem of opioid dependency in this patient group. • The Committee noted the evidence, the lack of national guidance to recommend the use of lignocaine infusions for chronic pain management and the local clinical input, as well as made a reference to the TVPC Ethical Framework regarding clinical effectiveness of interventions. The Committee agreed to recommend a 'not normally funded' position due to the lack of evidence for the clinical effectiveness of lidocaine intravenous infusions for chronic pain. • The change in provision of care for patients was discussed with a concern regarding current patients in the lidocaine pathway. It was proposed that patients who are already being treated may complete their pathway but no new patients should be commenced on infusion therapy. However, this will be for local CCG decision. **ACTION: The Clinical Effectiveness team to draft a policy recommendation: Lidocaine infusions for chronic pain and circulate for comment. Comments to be received within the 2 week feedback period following issue.**

9.	**Paper 18-037 – Review: Ethical Framework 'Exceptionality'**
9.1	The Committee asked for the 'exceptionality' paragraph in the Ethical Framework to be revisited following discussion at the TVPC training event in November 2018. Professor Chris Newdick together with CCG representation and members of the IFR and Clinical Effectiveness team considered research findings to produce a clear and meaningful explanation of 'exceptionality'. The refreshed wording focuses on the demonstration of exceptional clinical benefit in two distinct cases; when NICE technology appraisal or local clinical commissioning policies do not recommend use of the intervention or in cases in which the intervention has not been subject to NICE technology appraisal or local clinical commissioning policy. The committee felt that the updated wording was clear and easy to read and gave a full explanation on what is expected to be demonstrated for an IFR case as evidence for exceptional clinical benefit. The new definition will replace the current paragraph 8 in the Ethical Framework and will replace the current definition 'guide for patients and clinicians' on the IFR website. **ACTION: The Clinical Effectiveness team to update the Thames Valley Priorities Committee Ethical Framework paragraph 8 'Exceptional Need' and circulate for comment. Comments to be received within the 2 week feedback period following issue.**
10	**Paper 18-038 – Current Policy Updates**
10.1	Chair proposed that unless anyone has issues with the policy updates they can be progressed as agreed. It was noted that one item TVPC56 'Therapeutic use of facet joint injections and medial branch blocks for chronic neck pain' may need a further discussion in the next meeting. The Committee agreed. **ACTION: The Clinical Effectiveness team to update the policies identified in Paper 18-038 as requiring 'minor change' and circulate for comment. Comments to be received within the 2 week feedback period following issue.**
11.	**Paper 18-039 – Horizon Scanning**
11.1	Not reviewed due to time constraints.
12.	**Any Other Business**
12.1	**Paper 18-040 - Lymphoedema treatments brief**
	As part of the November 2017 TVPC topic scoring workshop the group scored review of lymphoedema services for primary lymphoedema. The reason for the initial topic request was 'Potentially large group of non-cancer related lymphoedema patients, high incidence of this condition in overweight individuals is increasing and pressure on services'. However, due to the low score and in-year priorities the topic has been rescheduled several times. In order to establish the aim of the review a topic scoping has been carried out. The Committee was asked to conder whether a review of primary lymphoedema/non-cancer lymphoedema is necessary, given national guidance on assessment and treatment of patients with lymphoedema in general is the same irrespective of its aetiology. The Committee acknowledged the potential unmet need for service for non-cancer lymphoedema and patients with chronic oedema, however, it was agreed that the availability and commissioning of pathways for these patients is CCG service provision rather than evidence base matter. The Committee agreed to take the topic off the work programme for this Committee.
12.1	**Paper 18-041 & 18-041a – Flash Glucose Monitoring systems**
	In March 2019 NHS England published the 'national arrangements for funding of flash glucose monitoring systems for appropriate patients with diabetes'. The NHS Long Term Plan announced that 'the NHS will ensure that, in line with clinical guidelines, patients with type 1 diabetes benefit from life changing flash glucose monitors from April 2019, ending the variation patients in some parts of the country are facing'.

12.1 Cont..	From 1st April 2019, for patients who satisfy the criteria set out by NHS England, they will reimburse CCGs for the on-going costs of flash glucose sensors. These criteria are estimated to represent up to 20% of England's type 1 diabetes population. The national funding arrangements are time limited to include 2019/20 and 2020/21, which will allow time for CCGs and prescribers to implement NICE guidelines and recoup the financial benefits of Flash Glucose Monitoring usage. Funding CCGs for the costs of sensors will be achieved by uplifting CCG resource allocation limits at each quarter end on the basis of prescribing data supplied by the Business Services Authority (BSA). TVPC 73 Flash Glucose Monitoring System - FGS (Freestyle Libre®) was based on the NHS England Regional Medicines Optimisation Committee (RMOC) 2017 Flash Glucose Monitoring Systems Position Statement. The new national arrangements for funding of flash glucose monitoring systems for the relevant patients with diabetes outlines a criteria for funding that differs from the original RMOC recommendation. The Committee acknowledge that it has to agree the national policy set out by NHS England. The TV heads of Medicines Optimisation have been working on this and drafting the documents on behalf of Frimley and are happy to share with the Committee and across the TV. It was also agreed that whist we use the national policy we expect to continue to use of the Thames Valley Patient agreement. **ACTION: East Berkshire to provide a copy updated documents incuding updated policy, patient agreement and frequently asked questions.** **ACTION: The Clinical Effectiveness team to update the TVPC 73 Flash Glucose Monitoring System - FGS (Freestyle Libre®) policy and the associated papers and circulate for comment. Comments to be received within the 2 week feedback period following issue.**
13.	**Next meeting**
	The next meeting will be **Wednesday 22nd May 2019, to be held in Meeting Room GU29/30 Bath Road, Reading RG30 2BA**
14.	**Meeting Close**
	The Chair thanked everyone for their contributions to the discussions and closed the meeting.