



*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 23rd November 2016

Conference Room A, 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
Heather Motion	Clinical Effectiveness Manager	SCWCSU
Rachel Finch	Clinical Effectiveness Administrator	SCWCSU
Jane Butterworth	Associate Director of Long Term Conditions & Medicines Management	Aylesbury Vale CCG & Chiltern CCG
Miles Carter	West Oxfordshire Locality Clinical Director	Oxfordshire CCG
Linda Collins	NICE Lead	Oxfordshire CCG
Frances Fairman	Medical Director – Clinical Strategy	NHS England – South Central
Dr Megan John	GP	Berkshire East CCGs
Catriona Khetyar	Head of Medicines Optimisation	Berkshire East CCGs
Dr Anees Pari	Senior Public Health Registrar	Bracknell Forest Council
Rosalind Pearce	Executive Director HealthWatch	Oxfordshire
Sarah Robson	Head of IFR	SCWCSU
Dr Mark Sheehan	Special Advisor - Ethics	University of Oxford
Cathy Winfield	Chief Officer	Berkshire West CCGs

Topic Specialists in Attendance for Agenda Items:

Dr Rustam Rea	Consultant Physician in Diabetes and Endocrinology	Oxford University Hospital
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Apologies:

Lindsey Barker	Medical Director	Royal Berkshire NHS Foundation Trust
Dr Tony Berendt	Medical Director	Oxford University Hospitals NHS Trust
Fiona Slevin-Brown	Director of Strategy & Operations	Berkshire East CCGs
Dr Graham Jackson	Clinical Chair	Aylesbury Vale CCG
Philip Murray	Chief Finance Officer	Chiltern & Aylesbury Vale CCGs
Dr Lise Llewellyn	Director of Public Health	Bracknell Forest Council
Tracey Marriot	Director of Innovation Adoption	Oxford Academic Health Science Network
Dr Clive Meux	Medical Director	Oxfordshire Health NHS Foundation Trust
Dr Minoo Irani	Medical Director	Royal Berkshire NHS Foundation Trust
Professor Chris Newdick	Special Advisor – Health Law	University of Reading
Jeremy Servian	IFR Manager	Oxfordshire CCG

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 declared quorate.
3.0	Declarations of Interest
3.1	None were declared.
4.0	Draft Minutes of the Priorities Committee meeting held 28th September 2016 (Paper 16-081) – Confirm Accuracy The draft minutes were accepted as a true record of the meeting.
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: 1) Dr Hussain to email a copy of her local flow chart to the CE team. 2) CE team 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 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. Action: Dr. John to develop a draft patient pathway for consideration at the February meeting.
5.2	Minutes of the Priorities Committee held in July 2016 – Action 11.3 – TVPC Meeting dates – Clinical Effectiveness team to investigate whether the TVPC meeting could be moved to an alternative Wednesday on the understanding that attendance would be assured. September Update: Dates identified where TVPC meetings clash with Provider Board Meetings for Oxfordshire & Berkshire West. The CE Team is to consider an alternative date for January 2017 meeting. November Update: <ul style="list-style-type: none"> • The next meeting will be Wednesday 1st February 2017 rather than in January 2017. Action: CE team to issue a revised meeting invitation. • It was agreed that for 2017/18 meetings will be held in Berkshire East. Action: CE team to identify a location and venue.

	<ul style="list-style-type: none"> To avoid clashes with Oxfordshire & Berkshire West Provider Board meetings in 2017/18 year, the follow dates are proposed: <ul style="list-style-type: none"> 24th May 2017 19th July 2017 20th September 2017 22nd November 2017 24th January 2018 21st March 2018 <p>Action: Members to confirm their availability</p>
5.3	<p>Minutes of the Priorities Committee held in September 2016 – Action 6.7 – Treatments for Painful shoulder-subacromial pain: Clinical Effectiveness team to draft a policy document and circulate for comment as per the usual process.</p> <p>Action Complete</p>
5.4	<p>Minutes of the Priorities Committee held in September 2016 – Action 6.8 – Policy documents relating to surgical procedures to include OPCS codes and indicative NHS tariff value.</p> <p>November Update: Primary codes have been included in recent policy statements but associated indicative costs have not. Following discussion the Committee agreed that due to the number of associated cost codes and the fact that they will quickly become out of date, policy documents are to include Primary OPCS codes only.</p> <p>Action: CE team to include Primary OPCS codes on future policy documents.</p>
5.5	<p>Minutes of the Priorities Committee held in September 2016 – Action 7.5 – Primary hip and knee replacement surgery: “It was noted that the coding of partial knee replacement as revision or conversion, is not clear, regardless of the revision surgery being included in the Specialised Orthopaedics Commissioning Specification and needs clarification”</p> <p>Update: There is some discrepancy regarding revision surgery terminology and what is covered by NHS England. When a partial knee replacement is revised it goes into the National Joint Registry as a revision procedure. The attending clinician present at the last meeting indicated that when a partial knee replacement is revised to a total knee replacement it becomes a conversion as opposed to a revision. CE team have been unable to find reference to the conversion terminology in the National Joint Registry or related NHS England documents.</p> <p>Action: CE team to seek clarification from NHS England specialised commissioning team for definitions used and their commissioning responsibility.</p>
5.6	<p>Minutes of the Priorities Committee held in September 2016 – Action 7.5 – Primary hip and knee replacement surgery: Clinical Effectiveness team to draft a policy document and circulate for comment as per the usual process.</p> <p>Action Complete</p>
5.7	<p>Minutes of the Priorities Committee held in September 2016 – Action 9.6 – General Hernia Policy: Clinical Effectiveness team to draft a policy document and circulate for comment as per the usual process.</p> <p>Action Complete</p>
6.0	Paper 16-082 – Policy Review: Insulin pumps
6.1	<p>There are two relevant NICE Guidelines which make recommendations on use of insulin pumps, TA151: Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus, and NG17: Type 1 diabetes in adults: diagnosis and management. The Committee noted that pumps are used alone, in conjunction with a continuous glucose monitor (CGM) or as integrated pumps with CGM built in. NICE TA151 is focussed on insulin pumps alone, whilst NG17 makes various recommendations about both the use of pumps and also around CGM use.</p>

	<p>The local Berkshire East and West policy was identified for review as CCGs were no longer responsible for commissioning insulin pumps for children. However information has now been received that paediatric commissioning of pumps is to be passed back to CCGs for April 2017. The Committee decided to proceed with a review of the policy for adults only.</p>
6.2	<p>The majority of patients administer their insulin by subcutaneous injection using prefilled disposable pens or reusable injection pens. A small number of patients are provided with insulin pumps by their specialist centres, due to difficulties in using a multiple daily injection (MDI) regime or inadequate glucose control. There are a number of insulin pumps available in the UK with variations in specifications, and more recently a number of devices with built in continuous glucose monitors have become available. There are several NICE guidelines available related to insulin pump use.</p> <p>NICE Technology Appraisal 151 recommends insulin pumps for type 1 diabetes where:</p> <ul style="list-style-type: none"> • attempts to achieve target HbA1c levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. • OR HbA1c levels have remained high (at 69 mmol/mol [8.5%] or above) on MDI therapy despite a high level of care <p>Other NICE clinical guidance suggests consideration of insulin pumps:</p> <ul style="list-style-type: none"> • Type 1 diabetes in adults, NG17 <ul style="list-style-type: none"> ○ As an option if patient uses real-time CGM ○ As a prioritised strategy in impaired hypoglycaemia awareness (other options recommended for consideration include structured education or continuous glucose monitoring (CGM)). ○ As an option if patient has gastroparesis • Diabetes in pregnancy, NG3, for insulin-treated diabetes (type 1, type 2 or gestational) <ul style="list-style-type: none"> ○ if adequate blood glucose control is not obtained by multiple daily injections of insulin without significant disabling hypoglycaemia. <p>The NICE guideline development group for NG17 suggested that an integrated pump and CGM system may be cost-effective although an assessment had not been carried out at the time. A 2015 systematic review and meta-analysis on restoration of impaired hypoglycaemia awareness supports the recommendation in NG17. No further published high quality studies have been identified on gastroparesis since the search carried out by NICE in 2014. The recently updated Cochrane Review on continuous subcutaneous insulin infusion versus multiple daily injections of insulin for pregnant women with diabetes did not include any further recent studies since the NICE 2008 recommendation.</p> <p>A pharmacy procurement tendering process for insulin pumps, some of which may include integrated continuous glucose monitoring (CGM), is currently underway on behalf of the Thames Valley and Wessex acute trusts however the contract will be available to CCGs; a decision is due in early December 2016.</p> <p>For this review total cost and activity data was not fully captured as some is recorded through pharmacy and some is invoiced directly to CCGs. CCGs may wish to investigate VAT exemption to reduce costs. Estimated costs sourced from the NICE NG17 costing template were presented.</p>
6.3	<p>The attending specialist stated that it would be helpful to have a local policy which addresses all NICE guidance, as currently a significant number of individual funding request applications are having to be made for the use of insulin pumps as well as continuous glucose monitors (CGM). Two groups of pump users were noted;</p>

	<ul style="list-style-type: none"> • informed, highly motivated people at high risk of complications but cannot attain HbA1c (glycated haemoglobin, indication of glycaemic control over previous 2-3 months) target • disengaged, unmotivated people with high HbA1c (e.g. >10%). <p>The attending specialist suggested that pregnant women with uncontrolled diabetes benefit from pump use. Evidence of reduced progression to long-term complications with lower HbA1c, and potential impact on diabetes associated admissions were noted. The specialist stated that potentially 3 admissions per year are avoided for every 10 patients using integrated pumps with CGM. The Oxfordshire pump service mainly uses the Medtronic device (with facility for integrated CGM) with a small number using patch pumps (no tubing, ideal for people regularly involved in sports/exercise).</p>
6.4	<p>The Committee discussed the balance of creating a policy that is specific but equitable or one that accommodates clinical judgement for individual needs. The Committee discussed the importance of patient commitment and ability to use/benefit from pump use. It was noted that the Oxfordshire pump service utilises individualised goal setting, e.g. reduction in the number of admissions, frequency of hypoglycaemic events, number of ambulance call outs, HbA1c reduction and restoration of hypoglycaemic awareness. NICE do not recommend a timeframe for assessment of achievement of goals. Insulin pump life and warranties are approximately 4 years. The specialist confirmed that patient contracts are in use in Oxfordshire to ensure benefit is assessed before pumps are replaced.</p>
6.5	<p>It was proposed that it would be appropriate to expand the use of insulin pumps beyond the recommendations of TA151 to include those with impaired hypoglycaemic awareness (IHA) or gastroparesis, in line with NG17. The Committee agreed that a policy should include elements of NG17, but had concerns around affordability and inability to quantify the benefits of pump use. It was noted that there is evidence around reduction of HbA1c, hypoglycaemia and complications but that direct impact on admission avoidance and complication reduction was difficult to quantify. NG17 suggests two cohorts of patients for consideration; those with gastroparesis or impaired hypoglycaemic awareness (IHA). These cohorts are considered to be very small in number but are associated with high admission rates.</p> <p>Post-meeting note: The attending specialist confirmed that Gold score ≥ 4 would be appropriate for definition of IHA criterion to demonstrate benefit from pump use and that goals for gastroparesis patients should reflect those identified in TA151.</p>
6.6	<p>The committee proposed that a policy should be based on TA151 with the addition of gastroparesis and IHA in line with NG17, including:</p> <ul style="list-style-type: none"> • timeframes for management with multiple daily injection use prior to pump consideration • stopping criteria, • information on individualised goals and timeframes, • confirmation that patients are committed and able to be compliant, • no replacement or upgrading within the 4 year lifespan of the agreed pump, • criteria for renewal after 4 years, • initiation must be by NHS multi-disciplinary team • privately funded pumps will not be supported (consumables) or replaced, • the most appropriate device with lowest acquisition cost be used. <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>

7.0	Paper 16-083 – Evidence Review: Freestyle Libre & other Continuous Blood Glucose Monitoring systems for adults with diabetes
7.1	Thames Valley CCGs have requested a review of Freestyle Libre and real-time continuous glucose monitors (CGM), in response to growing specialist interest in their use.
7.2	<p>CGM systems can be categorised as</p> <ul style="list-style-type: none"> • retrospective or real-time systems, • continuous or intermittent. • integrated within an insulin pump (continuous subcutaneous insulin infusion or CSII) or as a standalone device for use with either injections or a separate pump. <p>It was noted that CGM users continue to require self-monitoring of blood glucose (SMBG) for;</p> <ul style="list-style-type: none"> • calibration, • times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels or • if hypoglycaemia or impending hypoglycaemia is reported by the system or symptoms do not match the system readings. • driving <p>The DVLA do not currently accept CGM for drivers who use insulin, and therefore blood glucose monitoring is required to fulfil legal responsibilities.</p>
7.3	<p>There is no NICE technology appraisal for CGM. There are however criteria for use in NICE NG17, Type 1 diabetes in adults and NICE NG3, Diabetes in pregnancy. Both guidelines recommend that CGM should not be offered routinely. NG17 recommends criteria including patient commitment to use CGM at least 70% of the time, demonstrated engagement and an ability to use the equipment.</p> <p>There is evidence to support the use of CGM for patients with severe hypoglycaemia events and impaired hypoglycaemia awareness. There is also some evidence that CGM may support reduction in HbA1c levels, although the clinical significance of the levels vary in the studies. NG3 recommends a criteria for consideration of CGM use for these patients, and the recommendation is supported by results of a 2014 Cochrane review.</p> <p>Policy criteria for other CCGs were noted, including clarification of what initial management has been completed around patient compliance in education, carbohydrate counting, self-monitoring of blood glucose history, diet, definition of loss of hypoglycaemic awareness and a limit on the number of funded devices per annum.</p>
7.4	<p>There was no high quality evidence published at the time of writing the review paper and all studies were observational with mainly small cohorts. The studies suggest that use of CGM may be associated with improvements in HbA1c, hypoglycaemia and insulin regime compliance, with acceptable device accuracy.</p> <p>A 2016 randomised controlled trial on retrospective CGM in type 2 diabetes found that treatment guidance based on retrospective data did not improve glycaemic control in these patients.</p> <p>Two groups of potential users of CGM were noted;</p> <ul style="list-style-type: none"> • For sensor augmented pumps (SAP) - insulin pump users with unpredictable glucose levels, who require alarms due to loss of hypoglycaemic awareness, and have possibly lost employment or driving licence.

	<ul style="list-style-type: none"> • For Freestyle Libre – challenged with low or high glucose levels despite regime (either MDI or pump) and require data and information to inform glycaemic management. This represents the majority of potential users. <p>The Committee discussed the Freestyle Libre device. This device is not currently prescribable and not currently included in current national guidance. It represents a different type of system to real-time CGM and is not readily represented by evidence on retrospective monitoring apart from where data is only ‘read’ and utilised on an occasional basis e.g. at clinic visits. Everyday use of the system, therefore, falls into a novel category. Perceived advantages of Freestyle Libre include lower costs, absence of calibration requirement and longer sensor life. Disadvantages include absence of immediate alerts and reliance on user ‘read’ frequency.</p> <p>The attending specialist noted that a randomised controlled study had been published in November since the current review was circulated. This study on Freestyle Libre continuous use in type 1 patients showed a 40% reduction in time spent in hypoglycaemia and 50% reduction severe hypoglycaemia.</p> <p>Post meeting note: This was a randomised, controlled, multicentre, trial on Freestyle Libre continuous use in type 1 patients and included 328 patients across 23 European diabetes centres. The authors of this study identified a number of limitations which would have an impact on interpreting the results for this patient cohort:</p> <ul style="list-style-type: none"> • The study inclusion criteria of well controlled diabetes (HbA1c <7 · 5%) implies that participants were highly motivated and successful in their self-management compared with other populations. • The relative proportion of continuous insulin infusion users in the trial was higher than usually seen in most European type 1 diabetes populations and only adults were enrolled. Future studies would be needed to assess the effectiveness of this glucose monitoring system in younger age groups in addition to less well controlled and less motivated people with type 1 diabetes. • The trial took place over a period of 6 months and therefore there are limitations around expected compliance to device use over a longer period. No adjustment was made for multiple testing of secondary endpoints. Many of the endpoints, particularly those derived from sensor glucose values, are highly inter-related and should not be considered in isolation.
7.5	<p>Costs of CGM range from £700 initially with an annual recurring cost between £1,700 & £3,000 depending on the manufacturer. The initial cost of Freestyle Libre is £160 with an annual recurrent cost of approximately £1,400. The current insulin pump tender may include integrated pump systems and therefore it was felt that the outcome would be needed to inform a policy recommendation on devices.</p> <p>Berkshire and Buckinghamshire CCGs received 22 IFR requests in 2015-16 and 15 to September 2016 for CGMs. Oxfordshire CCG received three requests since April 2015. All were for upgrading or adding to existing pump systems.</p>
7.6	<p>The potential for CGM use to prevent future islet cell/pancreas transplant in some patients was discussed. Transplantation is commissioned by NHS England specialised services. Responsibility for funding trials of CGM prior to transplantation is unclear. The attending specialist suggested that SAP therapy may be appropriate for specific groups of patients on pumps, who have hypoglycaemia unawareness and might be eligible for a transplant. Information on SAPs provided by NICE DG21 and the associated costing statement was noted; no population estimates but individual cost and savings per system provided.</p>

7.7	<p>The use of CGM or SAP systems to restore hypoglycaemic awareness was discussed. The attending specialist suggested that the systems could be used short-term until restoration was achieved and then discontinued or switched to Freestyle Libre, with careful management. A brief outline was given, of the type of extra information available from CGM/Freestyle Libre and its impact on informing glycaemic management. Concern was expressed on potential for some patients to become anxious about variation, volume and detail of device readings. This may be addressed by encouraging a local community of device users to offer support and reassurance. It was noted that a holistic approach is required to identify patients capable of managing use of the systems, and specialist communication with GPs is encouraged.</p>
7.8	<p>The committee agreed that a policy is required to manage requests for CGM and Freestyle Libre. The limited current request data and lack of NICE resource impact assessment are barriers to policy development. It was suggested that Freestyle Libre should be considered with CGM due to its cost advantage for the patient group described above. It was agreed that a draft policy should be drawn up and a modelling exercise carried out to estimate associated resource impact. The committee proposed that the draft policy be based on NG17 and NG3 criteria for CGM, including:</p> <ul style="list-style-type: none"> • more than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause. • complete loss of awareness of hypoglycaemia. • frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities. • hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more. • pregnant women who have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) • pregnant women who have unstable blood glucose levels (to minimise variability) • to gain information about variability in blood glucose levels for pregnant women • confirmation that patients are committed and able to be compliant • initiation must be by NHS teams • stopping criteria <p>Criteria for use of Freestyle Libre would support only short-term use to identify reasons for problematic glycaemic control and will be considered at the February meeting.</p> <p>ACTION: Clinical Effectiveness team to draft a policy document and carry out a modelling exercise to estimate associated resource impact. This is to be brought to the February TVPC meeting along with a review of more recent evidence which has since become available and any relevant influence resulting from the insulin pump tender.</p>
8.0	<p>Paper 16-084 – Evidence Review: Sequential use of Biologics for Rheumatoid Arthritis</p>
8.1	<p>There are a large number of biologic therapy options available and endorsed by NICE technology appraisals (TA375, TA247, TA225, TA 195) for the treatment of rheumatoid arthritis and this review aimed to determine whether it is clinically and cost effective to use these therapies in a successional manner outside of the NICE recommendations. There are currently three related policies within the Thames Valley CCGs. The policy was developed by the South Central Priorities Committee in 2011 and updated in 2012 following the introduction of tocilizumab for the treatment of rheumatoid arthritis. Oxfordshire CCG updated their policy again in April 2016, it was noted that this includes a useful treatment flow diagram.</p>

	<p>NICE recommend that when a patient's first biologic fails rituximab is recommended, if that fails tocilizumab can be tried. Where rituximab is contraindicated or not tolerated tocilizumab or one of the other anti TNFs (Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, abatacept) is recommended. No further switching/cycling is recommended. The Committee noted that NICE Final Appraisal Document for TA375 suggests returning to conventional DMARDs as the next treatment option once the NICE recommended pathway for biological agents has been completed.</p>
8.2	<p>The committee discussed the evidence of clinical and cost effectiveness of sequential use of biologics outside of NICE TA guidance, including cycling through the different anti-TNFs. Systematic reviews indicated that patients still achieve significant clinical benefit from subsequent therapy, but highlight that there is a need for prospective randomised control trials comparing different treatments after failure. A cost effectiveness study carried out in 2013 indicates that switching from one anti-TNF agent to another after first-line treatment failure may not be a cost-effective treatment strategy. When non-TNF biologics are included in the sequence they are likely to be more cost-effective than anti-TNF specific cycling sequences. The Committee agreed that the evidence is insufficient to support switching and cycling through outside of NICE recommendations.</p>
8.3	<p>An additional element on this topic had been raised at the 2016 TVPC programme workshop to review the use of rituximab in seronegative patients and whether seronegative patients should be following the NICE recommended treatment pathway or if there is enough evidence to consider a separate treatment pathway for this cohort. The Committee noted that whilst there has been a significant number of small studies, results from systematic reviews are mixed with some concluding that there is no confirmed link between antibody status and the efficacy of anti-TNF therapy. A number of studies suggest there is a reduced response to rituximab in seronegative patients but it is not clear if the efficacy is sufficiently reduced as to warrant a change in the suggested NICE treatment pathway for these patients. It is also unclear whether this reduction in efficacy in seronegative patients is associated with only rituximab or if may also be associated with the other biologic treatments as well. It was noted that more studies in this subgroup of patients are needed to define the role of rituximab in seronegative patients. It was also highlighted that given this is a developing field the definition of seronegativity may need to be modified as newly identified autoantibodies emerge.</p> <p>The Committee did not feel that the evidence was currently sufficient to support the development of a separate treatment pathway for seronegative patients.</p>
8.4	<p>The Committee discussed the current local policies and agreed that the Oxfordshire policy should be updated and form the basis of a joint Thames Valley CCG policy. The Policy is to include:</p> <ul style="list-style-type: none"> • no further switching outside of NICE guidance • NICE treatment pathway recommended for all patients including seronegative patients <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> <p>Post meeting note: since the review was carried out NICE has published a further TA415 'Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor' https://www.nice.org.uk/guidance/ta415 'Certolizumab pegol, in combination with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other disease-modifying antirheumatic drugs (DMARDs) including at least 1 tumour necrosis factor alpha (TNF alpha) inhibitor, only if:</p>

	<ul style="list-style-type: none"> • disease activity is severe and • rituximab is contraindicated or not tolerated and • the company provides certolizumab pegol with the agreed patient access scheme. <p>Certolizumab pegol, as monotherapy, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other DMARDs including at least 1 TNF alpha inhibitor, only if:</p> <ul style="list-style-type: none"> • disease activity is severe and • rituximab therapy cannot be given because methotrexate is contraindicated or not tolerated and • the company provides certolizumab pegol with the agreed patient access scheme <p>This TA is added to the updated policy.</p>
9.0	Paper 16-085 – Policy Review: Frenuloplasty for Tongue Tie
9.1	<p>This review was requested following the benchmarking and national policy comparison exercise undertaken on behalf of the Committee in March 2016. The Committee requested review with a view to adopting a policy similar to that of Bedfordshire CCG’s current policy.</p> <p>The Committee discussed a number of CCG policies for frenuloplasty in tongue tie. The Bedfordshire CCG policy is in two parts, supporting frenuloplasty for infant feeding difficulties and speech problems for older children and adults.</p> <p>Key points include:</p> <ul style="list-style-type: none"> • for infant feeding the procedure is recommended for children under 3 months with perceived breastfeeding difficulties when carried out as an outpatient procedure. • for older children and adults with speech problems; the criteria include age of at least a 5years of age and stipulates that a speech and language therapist has assessed the patient for referral.
9.2	<p>There are two pieces of NICE guidance relating to frenuloplasty for tongue tie. For postnatal care up to 8 weeks after birth, NICE recommends (NICE Clinical Guideline CG37, 2015) that tongue-tie can be assessed and if found can be non-urgently referred. NICE Intervention Procedure Guidance (NICE IPG149, 2005), Division of ankyloglossia (tongue-tie) for breastfeeding notes that there are no major safety concerns about division of ankyloglossia (tongue-tie) and limited evidence suggests that this procedure can improve breastfeeding.</p> <p>The Committee considered the output from a 2016 Canadian Health Technology Appraisal which concluded that the procedure was safe and may confer benefit to the mother and baby. The review highlighted the positives about the maternal assessed outcomes of breastfeeding but noted that the evidence underlying these conclusions comes primarily from poor-quality non-randomised studies and does not adequately address the question of whether frenectomy provides a meaningful incremental benefit over other treatments or procedures to improve breastfeeding, particularly in the long-term. A 2015 systematic review on non-breastfeeding outcomes, including speech, found only poor quality evidence and was unable to draw conclusions on the impact of the procedure.</p>
9.3	<p>The Committee noted that whilst all local acute trusts have outpatient clinics to carry out the procedure, there is some variation as to how patients are referred and regarding advice prior to referral for the procedure.</p>

	<p>Specialist feedback from local clinicians was fed into the discussions. The following points had been raised:</p> <ul style="list-style-type: none"> • lack of evidence to support procedure regarding suggested outcomes • there are children who may need this procedure not for breastfeeding and speech but around neurological disabilities, or ulceration and pain, drooling etc. • referrals to be made urgently rather than non-urgently, • community midwife training for identification of significant tongue-tie • with speech indications consider from age 4 and over not age 5 and over, • an emphasis on breastfeeding support & positioning before referral takes place <p>The Committee also reviewed the inpatient and outpatient activity and associated costs. Having taken consideration of local data, local specialist feedback and the evidence for clinical and cost effectiveness of frenuloplasty for tongue tie, the Committee concluded that a policy was not required for the Thames Valley at this time.</p>
10.	Any Other Business
10.1	<p>Surgery for painful big toe: Bunions. This policy was originally agreed at July 2016 Committee meeting. The draft policy was amended following comments from the specialist regarding reference to 'no passive correction of the big toe' which was removed and reissued to CCG's for ratification. However, it was noted that the policy proposal was rejected by Berkshire East CCGs as they did not feel conservative treatment for three months was long enough. The Committee discussed the length of conservative treatment and agreed to retain this recommendation as this criteria applied to patients with <i>severe</i> pain or deformity. It was noted there was no NICE guidance and the reference to 3 months conservative treatment comes from Royal College of Surgeons Commissioning Guide.</p> <p>The Committee considered the comments and agreed the following:</p> <ul style="list-style-type: none"> • removal of reference to the passive correction of the big toe • to provide an explanation to Berkshire East that the 3 month timescale only applies to people with really severe deformity and pain. <p>ACTION: Clinical Effectiveness team to discuss with Berkshire East</p>
10.2	The Committee agreed that the policy changes recommended above were not felt sufficient to require patient consultation.
10.3	The Committee welcomed Rosalind Pearce who will be representing HealthWatch at future TVPC meetings.
10.4	The Committee noted that Paul Harris will no longer attend the Committee; Paul has been a long standing GP member of the Committee and thanks were expressed for his valued contribution.
10.5	The Committee also extended their thanks and appreciation to Heather Motion who leaves the Clinical Effectiveness team at the end of December and will no longer attend the meetings.
11.	Next meeting
	The next meeting will be Wednesday 1st February 2016, held in Conference Room A, Jubilee House, Oxford, OX4 2LH. NOTE: this is a change from the date previously advised.
12.	Meeting Close
	The Chair thanked everyone for their contributions to the discussions and closed the meeting.