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 21st March 2018

Conference Room, 2nd Floor, Albert House, Queen Victoria Road, High Wycombe HP11 1AG

Attendance:

Alan Penn	Lay Member Chair	Thames Valley Priorities Committee
Jane Butterworth	Associate Director of Long Term Conditions & Medicines Management	Buckinghamshire CCGs
Shairoz Claridge	Operations Director Director for Planned Care	Newbury and District CCG Berkshire West CCGs Federation
Linda Collins	Clinical Effectiveness Manager (CCG)	Oxfordshire CCG
Mike Fereday	Vice Chair HealthWatch	West Berkshire
Darrell Gale	Acting Strategic Director of Public Health	Berkshire
Edward Haxton	Deputy Finance Director	Berkshire West CCGs
Thalia Jervis	CEO, HealthWatch	Buckinghamshire
Dr Megan John	GP, Berkshire East CCG Lead	Berkshire East CCGs
Chris Newdick	Professor of Health Law	University of Reading
Dr Jacky Payne	GP	Berkshire West CCGs
Raju Reddy	Secondary care Consultant	Berkshire West CCGs
Amaka Scott	Commissioning Interfacing Pharmacist	Berkshire West CCG
Dr Mark Sheehan	Special Advisor – Ethics	University of Oxford
Dr Karen West (For Dr Graham Jackson)	GP	Buckinghamshire CCGs

In Attendance:

Laura Tully	Assistant Director of Clinical Quality	SCW
Tiina Korhonen	Clinical Effectiveness Lead	SCW
Kathryn Markey	Clinical Effectiveness Manager	SCW
Kate Forbes	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 – Joint Replacement (shoulder) & 10.1 Subacromial Decompression of the Shoulder (		
Mr Tom Pollard	Consultant Orthopaedic Surgeon British Orthopaedic Association Community Champion	Royal Berkshire NHS Foundation Trust
Mr Christopher Little	Consultant Hand & Upper Limb Surgeon	Oxford
Professor Ofer Levy	Consultant Orthopaedic Shoulder Surgeon	Berkshire Independent Hospital, Reading
Item 8 – Sequential use of Biologics in Rheumatoid Arthritis (3.35pm)		
Dr Catherine Swales	Consultant Rheumatologist	Oxford University Hospital Nuffield Orthopaedic Hospital, Oxford
Dr Lorraine O'Neill	Consultant Rheumatologist	Oxford University Hospital
Maire Stapleton (via telephone - connection not maintained)	Formulary Manager	Buckinghamshire Healthcare NHS Trust
Dr Magliano Malgorzata (via telephone at 3.45pm)	Consultant Rheumatologist and Rheum SDU Lead	Buckinghamshire Healthcare NHS Trust

Apologies:

Sarah Annetts	IFR Manager (Clinical)	SCW
Lindsey Barker (LB)	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
Frances Fairman	Assistant Director Clinical Strategy	NHS England, TV Area Team
Dr Mark Hancock	Medical Director	Oxford Health NHS Foundation Trust
Rebecca Hodge	Clinical Effectiveness Manager	SCW
Dr Graham Jackson	Clinical Chair	Aylesbury Vale CCG
John Lisle	Chief Officer	Berkshire East CCGs
Tracey Marriott	Director of Innovation Adoption	Oxford Academic Health Science Network
Eleanor Mitchell	Operations Director	South Reading, Berkshire West CCG
Louise Patten (LP)	Accountable Officer	Buckinghamshire CCGs
Rosalind Pearce (RP)	Executive Director HealthWatch	Oxfordshire
Sarah Robson	Head of IFR	SCW
Sangeeta Saran	Head of Operations	Berkshire East CCG
Fiona Slevin-Brown	Director of Strategy & Operations	Berkshire East CCGs

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.
2.2	The meeting of 24th January 2018 was not quorate. **Action: Clinical Effectiveness team to circulate minutes detailing any policy recommendations made by the Committee to absent members for approval. Action Complete**
3.0	**Declarations of Interest**
3.1	None were declared
3.2	**Non-quorate Committee Meeting of 24th January 2018**
	The minutes detailing policy recommendations made by the 24th January Committee were circulated to absent members for approval. However, full approval was not agreed by an absent Committee member due to concern that the minutes of the November 2017 meeting were not a true representation of the discussion that took place in relation to the recommendations arising from Paper 17-026 Draft Policy Review: Flash Glucose Monitoring System (FGS) and proposed Patient Agreement Forms. These resulted from recommendations by the November 2017 Committee and tabled at the January 2018 Committee meeting. The concern was to query the action in relation to the financial impact assessment and expectation that further assessment was to be submitted to the Committee in January.
	The committee acknowledged that a long discussion took place at the November 2017 meeting in regards to the clinical as well as estimated financial impact of making a recommendation for the use of FGS. It was also noted that new local data may have emerged since the assumptions made in November, in particular in Berkshire West, increasing the financial pressure. **November minutes 9.5** indicates the Committee examined the evidence and financial information available at that time. The financial data was mainly based on the national estimates and modelling based on the Association of British Clinical Diabetologists – ABCD data. The Clinical Effectiveness team were asked to use the best available data when preparing the governing body papers. There was no request as a separate action to return the financial impact assessment to the Committee prior to sending the draft policy recommendations to CCGs for agreement. However, as the Clinical Effectiveness team received significant clinical feedback on the draft policy, it was brought back to the January 2018 Committee for further discussion centred on clinical detail, not to revisit any financial information. The Chair proposed that the November minutes 9.5 provided a reasonable account of what was discussed at the meeting and the committee agreed with this.
	The chair also proposed that the committee consider the matter raised that there was now new data available and whether the committee should re-examine the recommended FGS policy. It was recognised that the committee needs to be confident in the recommendation it is making and revisiting a decision needs to be justified i.e if there is new evidence available. It was acknowkdged that the concerns raised re FGS were related to cost pressures rather than new clinical or cost effectiveness evidence. It was also noted that the final decision whether the Committee recommendation is adopted will rest with the individual CCGs. It was agreed that the draft policy was as robust as possible and was accompanied by the proposed Patient Agreement Forms to support data collection and appropriate local FGS use. However, as the CCG estimates of eligible patient numbers vary the affordability and longer term impact needs to be monitored. The committee agreed that a joint audit to monitor the update and outcomes of the FGS use would be helpful. It was agreed that JB will co-ordinate the development of the audit with the support from the CCG representatives. **ACTION: JB to contact each TVPC CCG representative to discuss and agree the audit criteria and time frame to monitor the use of FGS.**

4.	**Draft Minutes of the Priorities Committee meeting held 24th January 2018 - Confirm Accuracy**
4.1	**The draft minutes were accepted as a true record of the meeting.** **Refer to 3.2 above**
5.	**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** - **September 2017 Update:** A working group has been formed; an initial meeting is being arranged. **November 2017 Update:** Two GP's, from Berkshire East and Berkshire West are looking at the primary care fertility pathway, they will consult with clinicians from all of the relevant localities to produce a final draft. A report will be presented to this Committee, provisionally in March 2018. **March 2018 Update:** Report to be presented in May 2018.
5.2	**Minutes of the Priorities Committee held in September 2017 – Action 7.5 – Paper 17-013 Treatment Pathway for Adults with Attention Deficit Hyperactivity Disorder (ADHD)** The Committee noted that shared care pathway protocols vary across the Thames Valley CCGs and agreed it would be of benefit to have a common shared care protocol. Thames Valley Accountable Care System is currently undertaking work to generate an overall shared care protocol; details to be provided to the Committee when available. An update to be provided at the March 2018 meeting. **March 2018 Update:** Lindsay Barker to provide an update at the May 2018 meeting.
5.3	**Minutes of the Priorities Committee held in November 2017 – Action 12.2 – Any Other Business – Referral pro forma** Sarah Robson to discuss the MSK referral pro forma criteria with Eleanor Mitchell and provide an update to the Clinical Effectiveness team and update the clinical team. **March 2018: Action Complete**
5.4	**Minutes of the Priorities Committee held in January 2018 – Action 6.5 - Paper 17-026 a, b & c - Draft Policy review: Flash Glucose Monitoring and proposed Patient Agreement Forms** Following circulation of the draft policy statement Flash Glucose Monitoring Systems (FGS) for patients with Type 1 diabetes, feedback received by the Clinical Effectiveness team included amendments and proposed additions to the content agreed by the Committee at the November 2017 TVPC meeting. As the changes were more than formatting the Committee were asked to revisit the recommendations. Following discussion the following actions were agreed: **ACTION 6.5:** Clinical Effectiveness team to amend and check the HbA1C units in the policy and patient agreements. **ACTION Complete** **ACTION 6.5.1:** Clinical Effectiveness team to amend the FGS policy continuation criteria to state that all patients should perform >4 scans per day and then any one of the other criterion. **ACTION Complete** **ACTION 6.5.2:** Clinical Effectiveness team to remove the words "or agreed personal targets" from the FGS policy discontinuation criteria. **ACTION Complete** **ACTION 6.5.3:** Clinical Effectiveness team to add 'either' to the threshold for 'Frequent admissions (>2 per year) with diabetic ketoacidosis (DKA) or hypoglycaemia' and amend the draft Flash Glucose Monitoring System (Freestyle Libre®) policy and patient agreement forms, as outlined in the amended draft policy, and circulate for final comments. Comments to be received within the 2 week feedback period following issue. **ACTION Complete**
5.5	**Minutes of the Priorities Committee held in January 2018 – Action 7.4 - Paper 17-027 – Evidence Review: Knee Arthroscopy for the Treatment of Meniscal Tears** Clinical Effectiveness team to draft a policy recommendation: Knee Arthroscopy for the Treatment of Meniscal Tears, and circulate for comment. **ACTION Complete**

5.6	**Minutes of the Priorities Committee held in January 2018 – Action 8.5 - Paper 17-028 – Evidence Review: Diagnosis of Foetal Alcohol Syndrome Disorder (FASD) and Alcohol Related Neurodevelopment Disorder (ARND)** Clinical Effectiveness team to draft a policy recommendation for the diagnosis and treatment of FASD in children, adolescents and adults, and circulate for comment. **ACTION Complete**
5.7	**Minutes of the Priorities Committee held in January 2018 – Action 9.4 - Paper 17-029 – Policy Update: Gallstones (treatment of patients with previously symptomatic gallstones who are now free of symptoms)** Clinical Effectiveness team to draft a Gallstones (treatment of patients with previously symptomatic gallstones who are now free of symptoms) policy 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 2018 – Action 10.2 - Paper 17-030 – Update: Cataract Surgery – post final NICE guidance publication** Clinical Effectiveness team to re-circulate TVPC 60 policy Cataract Removal in Adults – Threshold for Surgery for comment. Comments to be received within the 2 week feedback period following issue. **ACTION Complete**
5.9	**Minutes of the Priorities Committee held in January 2018 – Action 11 - Policy Update: Hip and Knee Revision – MHRA MDA Metal on Metal Hip Replacement** Clinical Effectiveness team to update TVPC55 - Primary hip and knee replacement revision surgery to include reference to the Regulatory Agency (MHRA) Medical Device Alert (MDA) on metal on metal (MoM) hip replacements. **ACTION Complete**
5.10	**Minutes of the Priorities Committee held in January 2018 – Action 13.1 – Any Other Business – TVPC Meeting Dates and Venue for 2018-19 programme year** Berkshire West is due to host TVPC meeting with effect from 23rd May 2018, the following actions were agreed: **ACTION 13.1:** Shairoz Claridge to make enquiries with Bath Road Reading for room availability to accommodate TVPC meeting on four dates in 2018. **ACTION Complete** **ACTION 13.1.1:** Clinical Effectiveness team to issue calendar invites to Committee members for 2018-19 meetings. **ACTION Complete**
5.11	**Minutes of the Priorities Committee held in January 2018 – Action 13.2 – Any Other Business – Biologics in Rheumatoid Arthritis Policy.** **Refer to agenda item 8.**
6.	**Paper 17-033 – Evidence Review: Shoulder Replacement for Osteoarthritis, Rheumatoid Arthritis and Rotator Cuff Arthropathy**
6.1	Thames Valley CCGs requested a review of joint prosthesis (other than hip and knee) to inform a potential threshold policy development. The request identified that these are low volume but high cost treatments and that with no current policy in place, there may be variation in practice. The focus of this review was shoulder replacement. Several conditions can cause shoulder pain, loss of range of motion and degeneration leading to shoulder joint replacement. The evidence review focused on osteoarthritis (OA), rheumatoid arthritis (RA) and rotator cuff arthropathy which to have the highest surgical activity rates nationally. Types of shoulder arthroplasty include standard total shoulder replacement, reverse shoulder replacement and hemiarthroplasty. There is a lack of robust research literature in relation to shoulder replacement and reverse shoulder replacement for OA, RA and rotator cuff arthropathy. Systematic reviews are mainly based on case series with small numbers of patients. However, the National Joint Registry (NJR) collects data and patient reported outcome measures using the Oxford Shoulder Score (OSS). Activity and spend data was shared with the meeting. NICE are due to publish a Hip, Knee and Shoulder Replacement clinical guideline in 2020. There is current NICE guidance for OA and RA. The NICE guidance for OA & RA states that surgery should not be delayed until there is significant functional impairment. However neither the OA or RA guidelines provide guidance for thresholds

	for surgery. Conservative options are limited (mostly to analgesia) if a patient has a severely damaged shoulder joint.
6.2	The attending clinicians reported that gaining evidence in the form of robust RCT's for surgical intervention was difficult as it is not possible to complete sham operations for shoulder replacements. The clinicians reported that the British NJR has been collecting data on shoulder replacement patients for the last 4-5 years, is the largest international joint registry and the only one to include PROM's data. The 2015-16 Annual Report demonstrated statistically significant median improvements in the PROM scores for all types of implantation of between 13 and 21 points (OSS scale 0-48). This data has contributed to the acceptance that there is considerable benefit to be derived from shoulder arthroplasty, with on-going research and NJR data analysis to determine the optimal implant for different patient groups, and to determine factors that predict early failure. The clinicians reported the following concerns regarding the use of steroid injections: 1. There is a risk, albeit low, of infection and inflammation with each injection and the risk of subsequent infection of the joint replacement is increased. 2. There may be a cumulative risk of rotator cuff atrophy and failure if an arthritic shoulder is repeatedly injected with steroids. 3. The clinicians also noted that if surgery is delayed it can lead to further erosion of the articular surface reducing surgical options. Revision rates; The clinicians reported that the revision rate for shoulder replacements is not high compared with other arthroplasty. Weight loss; the clinicians reported that weight loss / gain does not affect shoulder function or outcomes after surgery. In general the use of anaesthetic in patients with obesity carries more risk. Of note is that the use of biologics to treat RA has reduced the number of shoulder replacement surgery over the last 20 years.
6.3	The Committee considered the evidence and specialist feedback, acknowledged the limited conservative measures available, and the need to refer for surgery prior to severe functional limitation, therefore the committee agreed that policy development was not necessary.
7.	**Paper 17-034 & 17-035 - Evidence review: Iron Chelation for Myelodysplastic Syndromes**
7.1	Due to time constrains this item was deferred to the 23rd May 2018 meeting.
8.	**Paper 17-036 – Policy update: Sequential use of Biologics in Rheumatoid Arthritis**
8.1	Thames Valley CCGs requested a review of TVPC policy 51: Sequential use of Biologics in Rheumatoid Arthritis (RA), policy recommendation developed in March 2017. The review was to focus on new guidance and/or evidence regarding cycling or switching biologics following an inadequate response to an initial biologic or intolerance to an initial biologic to ensure the policy aligns to NICE guidance.
8.2	Since March 2017 there have been three new NICE Technical Appraisals (TA) published; one is an IL-6 inhibitor and two are novel therapies - JAK kinase inhibitors, which have a different mode of action to existing therapies, are oral preparations and are non-biologic. There were also updates to the European League Against Rheumatism (EULAR) recommendations, one new systematic Cochrane review and two systematic reviews which investigated evidence for the sequential use of biologic treatments in RA. No new evidence was available for the use of biologics in seronegative patients. No new randomised control trials (RCTs) were found that compared different biologics after an inadequate response to an initial biologic. Systematic reviews confirmed that sequential treatment can be an effective strategy after failure of initial biologic therapy, but that head to head trials were needed to determine whether second line treatment with anti-TNF or other biologic treatments would be most effective. No new evidence was found in relation to how the efficacy of biologic treatments may differ by RA serotype.

8.3	The attending clinicians from OUH expressed two concerns relating to the use of Rituximab: • For a significant group of patients who have both joint disease and lung disease; rituximab is the only biologic agent that will effectively treat both. The clinicians therefore propose that this is offered as a first line treatment for this group of patients. • The current pathway only allows use of rituximab if the patient is also on methotrexate. However, methotrexate can be detrimental to lung function, a concern for patients with interstitial lung disease (ILD). The clinicians reported that they currently prescribe rituximab with another disease-modifying anti-rheumatic drug (DMARD) if possible. They also recommended the use of rituximab without methotrexate in these circumstances (proposed use is off licence). Other points raised through discussion: • The clinicians advised that the maximum number of treatments should be three in total, and classed patients who are multi-resistant as those that have failed 2 agents with different mechanisms of action, e.g. TNF inhibition and B cell depletion via rituximab. • The clinicians described intolerance and how it depends on the agent, for rituximab, it may be an infusion reaction or anaphylaxis. For TNF agents it varies from mild reaction, such as injection site reactions to anaphylaxis to potential issues of white cell count toxicity, rarely liver function issues, some people may get intolerable headaches. IL-6 inhibitor can be associated with exacerbation of diverticular disease. • The clinicians commented that their audit data of around 200 patients showed no difference in disease activity score (DAS scores) between patients on rituximab plus methotrexate and patients on rituximab where methotrexate was discontinued due to toxicity. The Committee asked the specialist clinicians to provide a copy of their audit data. Feedback re patient concerns were conveyed by Ailsa Bosworth, Chief Executive of National Rheumatoid Arthritis Society and noted, in particular on the notion of choice early on between TNF inhibition and rituximab, to allow clinician expertise when faced with complex patients. **ACTION: Specialist clinicians to provide the Clinical Effectiveness team with a copy of their rituximab audit report data.**
8.4	Dr Magliano Malgorzata Consultant Rheumatologist and Rheum SDU Lead (Buckinghamshire Healthcare NHS Trust) joined via telephone – at 3.45pm
8.5	On the basis of the evidence review and clinical feedback, the Committee asked that the Berks West algorithm be used as a basis for the policy update to include: • A separate pathway for patients with lung disease to allow Rituximab to be used first line and without methotrexate • Title and text change to reflect the new technologies available • Maximum of 3 treatments and statement relating to the use of cost effective biosimilars • Exceptions to the exit criteria if there is a clear reason for reduced response to a treatment with an expectation that they will improve again The potential financial impact of the policy update was also discussed. NICE considers that the new treatments will not have a significant impact on resources as they are an option alongside current standard treatment options. **ACTION: Clinical Effectiveness team to draft a policy recommendation update: Use of Biologics in Rheumatoid Arthritis and circulate for comment. Comments to be received within the 2 week feedback period following issue.**

9.	**Paper 17-037: Exception Access to Treatment - SB v NHS England (2017) Judicial Review Outcome: IFR Challenge re treatment for Phenylketonuria**
9.1	NHS England has been criticised in a decision about "exceptionality" in SB v NHS England case. The Committee had a brief of the judicial review where a child with Phenylketonuria (PKU) and autism was denied access to Kuvan to help manage his condition. NHS England (NHSE) had rejected an IFR application that SB should have access to Kuvan as an 'exceptional' patient. The reasons why NHSE rejected the application for 'exceptionality 'are not clear as the advice received indicated it was a highly exceptional case. The IFR Panel used NHSE's own description of exceptional clinical circumstances, i.e. "there must be an NHS Commissioning policy in place that describes the availability of the requested intervention and your patient must demonstrate that they are both 1. Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition AND 2. Likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition. The combination of the two conditions (autism and PKU) is reflected in a total of 1 or 2 individuals in the whole of the UK. Also the NHSE had previously accepted the evidence of effectiveness of Kuvan. The judge said the IFR Panel's conclusion contradicted the view of NHSE's Clinical Commissioning Policy (CCP) and described their decision as irrational. NHS England reversed its decision and committed to fund this treatment. In light of the above case the Committee agreed that the current TVPC Ethical Framework offers a good guidance for local decision making.
10.	**Any Other Business**
10.1	**Paper 17-038 – Policy Clarification: TVPC50 Subacromial Decompression of the Shoulder**
	Policy TVPC50 for Subacromial decompression of the shoulder was developed in September 2016. The Committee asked the Clinical Effectiveness team to revisit the wording of the criteria as individual funding request and prior approval teams have found the wording of the policy conflicting. The original policy was related to shoulder impingement surgery and a treshold for referral for surgical opinion was agreed. The current wording however, also incude a statement that 'Primary subacromial decompression in isolation is not normally funded unless the patient has a massive subacromial spur scoring the muscle and may otherwise require a cuff repair'. The intention of the policy was to address the tresholds for surgery for patients who have pain due to impingement, acknowledging that impingement surgery can also be carried out as part of rotate cuff injury repair. The committee agreed to clarification of wording to remove the paragraph 'Primary subacromial decompression in isolation is not normally funded unless…' and clarify the indication for surgery in the title of the policy. **ACTION: The Clinical Effectiveness team to change TVPC50 policy title from 'Subacromial Decompression of the Shoulder' to 'Subacromial Decompression for shoulder impingement and remove the last paragraph in the current policy.**
11.	**Next meeting**
	The next meeting will be **Wednesday 23rd May 2018, to be held in Conference Room, Albert House, High Wycombe HP11 1AG.**
12.	**Meeting Close**
	The Chair thanked everyone for their contributions to the discussions and closed the meeting.