Northern, Eastern and Western Devon Clinical Commissioning Group

Status update to Plymouth Health and Wellbeing Committee regarding NEW Devon CCG potential interim disinvestments

Recommendation: The committee should consider and note the current position in relation to disinvestments.

1. Executive Summary

1.1 In October NEW Devon CCG published a list of services which it was considering for disinvestment. The need to consider de-prioritising certain services was a consequence of prioritising urgent services, particularly over the winter period.

1.2 That list of services was subject to clinical review during November and Equality & Quality Impact Assessment. Recommendations were reached to limit certain treatments on the basis of evidence and impact. These were due to be 'Interim Commissioning Positions' in force for a 12 to 18 month period, during which time fuller consultation and more detailed review would take place. The outcome in that 12 to 18 month period would be to either amend, revoke or make permanent the Interim Positions as Clinical Policy.

1.3 However, in the course of the last two months, and following feedback and engagement, the CCG's approach has altered. The services under review are believed to be amenable to referral *guidance* to clinicians, rather than enforced policy on the whole. For clarity, enforced restrictions on services via Interim Commissioning Positions are now not being implemented. Instead we will develop guidance for clinicians during the final quarter of 14/15. For a few measures, covered in this paper, we will move to a full policy position during April via the usual Clinical Policy Committee infrastructure and governance.

This paper was originally requested as an account of the process and impacts associated with Interim Commissioning Positions. Given the alteration in approach away from enforced restrictions, the paper provides an update on the current status of previously proposed measures as a basis for discussion with Devon Health and Wellbeing Scrutiny Committee.

2. What has been decided? Measures under consideration and their current status

2.1 Table 1 lists areas for which the CCG had intended Interim Commissioning Positions. The table also displays the way in changes to service provision in those areas will now be considered.

2.2 These measures were generated from a clinically-led workshop of 18 GPs from across Devon, the CCG Director of Nursing, CCG Clinical Chair, an out-of-area secondary care consultant member of the CCG's Governing Body and Public Health consultants from Devon and Plymouth. A summary of the clinical rationale associated with these is provided at Appendix A.

Table 1. Proposed Interim Commissioning Positions and their status under the revised implementation approach

Area under consideration for Interim Commissioning Position	Summary of proposed Interim Commissioning Position	How this clinical area will now be progressed
Weight loss in obese patients prior to routine surgery	Where surgery is not immediately clinically necessary and where weight loss would be beneficial for clinical outcomes and/or peri-operative risk, a requirement for patients to achieve 5% weight loss if they have a Body Mass Index > 35.	To be developed as Referral Guidance to clinicians with supporting services for patients.
8 weeks smoking cessation prior to routine surgery	Where surgery is not immediately clinically necessary, a requirement for patients to cease smoking for 8 weeks prior to their operation.	To be developed as Referral Guidance to clinicians with supporting services for patients.
Funding of 2nd hearing aid	Unless other sensory or disabling factors exists, 2nd hearing aids would not be routinely funded.	Not being pursued as a commissioning position or policy. Further work to understand whether contractual levers exist to identify any Supplier-led demand for hearing aid services.

Ear microsuction for the removal of wax	Unless for the treatment of infection or due to other factors which make ear syringing in primary care clinically inappropriate, no routine funding of wax removal by microsuction.	To be developed as Referral Guidance to clinicians with non-hospital alternatives developed for patients.
Criteria for cataract surgery	Enhancement of policy to bring in to line with more restrictive policies from elsewhere in the UK. Driving level vision to be funded (for drivers and non drivers). Tighter restrictions than currently for the 2nd eye.	To be considered by the usual Clinical Policy Committee route to arrive at a policy for the treatment of cataracts.
Shoulder surgery	Prior approval by a CCG clinical panel required for shoulder surgery in recognition of poor evidence associated with shoulder surgery.	No interim position being adopted. Further work ongoing with the British Orthopaedic Association, Chartered Society of Physiotherpists and local clinicians to define best practice pathways to be commissioned.
Use of Avastin in the treatment of Wet Age-Related Macular Degeneration (Wet AMD)	A switch to the treatment recommended by the World Health Organisation for this condition. Requires a CCG position as the drug is unlicensed for that purpose in the UK, the manufacturers not having applied for a license.	This remains the CCG's commissioning intention. Work ongoing with local trusts and with other CCGs to develop the implementation.
Shockwave therapy in the treatment of tendinopathies	Interim suspension of this service, in recognition of equivocal evidence and it not being universally available.	No interim position being taken. Referral guidance for clinicians being developed.

Appenidx A: Summary evidence in relation to urgent & necessary measures

1. The clinical rationale for the areas of disinvestment which were being considered by NEW Devon CCG is provided below. Please note that these follow a rapid review process to support what had been intended as Interim Commissioning Positions (ie temporary policy) but which will now be developed predominantly as clinical guidance to clinicians.

Use of Avastin in the treatment of Wet AMD

Smoking cessation prior to routine surgery

Weight loss prior to routine surgery

Second hearing aids

Cataracts

Ear microsuction

Suspension of shockwave therapy for tendinopathies

Prior Approval for shoulder surgery

2. Use of Avastin in the Treatment of Wet AMD

The use of bevacizumab (Avastin) rather than ranibizumab (Lucentis) or aflibercept (Eylea) in the treatment of Wet AMD reflects the following:

- Bevacizumab is the World Health Organisation's recommended treatment for Wet AMD[1].

- Although the manufacturers of bevacizumab report that it has a higher molecular weight and a higher particulate rate than they would specify for use in the eye, the Cochrane Collaboration's 2014 review of nine non-industry funded RCTs concluded that, "Health Policies for the utilisation of ranibizumab rather than bevacizumab as a routine intervention for neovascular AMD for reasons of systemic safety are not sustained by evidence."[2]

- The IVAN head to head trial of ranibizumab and bevacizumab in the UK found no difference in frequency in safety outcomes between bevacizumab and ranibizumab.[3]

- The IVAN trial found the effectiveness of bevacizumab to be neither better nor worse than ranibizumab in its measure of clinical effectiveness (ie best corrected distance visual acuity BCVA).[4]

- Ranibizumab has been found not to be cost-effective in comparison with bevacizumab[5], both in classic AMD and where the disease is minimally occult or occult with no classic lesions[6].

- Novartis and Roche, manufacturers of ranibizumab and bevacizumab, have been found guilty in Italy of 'cartelising' the pricing of the two drugs, creating an artificial distinction between them which directs demand to the higher priced drug[7].

- The Royal College of Ophthalmologist's recent challenge to the NHS to be able to use bevacizumab rather than ranibizumab in the treatment of Wet AMD[8, 9]should be noted.

- The CCG also noted that in another condition, pharmacological management of neuropathic pain, NICE (CG173, 2013) recommends unlicensed use of a medication in the presence of a licenced alternative. Three of the four drugs recommended by NICE do not have a specific licence for the purpose recommended and off-label use is noted in the guidance.

3. Smoking cessation prior to routine surgery

Eight weeks' smoking cessation is to apply prior to routine surgery. Procedures deemed to be immediately clinically necessary are excluded from this requirement.

Evidence considered by the CCG includes:

- A 2010 Cochrane review[10] on the interventions for preoperative smoking cessation suggests that stopping smoking four to eight weeks before surgery may reduce the risk of:
  - wound-related, lung and heart complications
  - prolonged bone fusion time after fracture repair
  - prolonged stay in hospital after surgery

- On the subject of the exact period of smoking cessation that is beneficial, most research finds that two months is of most benefit[11, 12, 13, 14].

- Providing pre-operative counselling and support for smokers awaiting surgery leads to a high quit rate compared to no support[15]. Therefore the preoperative period is a good period to offer smoking intervention.

- Compared with non-smokers and ex-smokers, smokers are more likely to stay longer in hospital, be admitted to an intensive care unit or die in hospital. A helpful NHS review, The Clinical Case for Smoking Cessation before Surgery[16], is provided by the UK National Smoking Cessation Conference. Specific risks include:
  - impaired pulmonary function such as increased mucus production, and damage to the tracheal cilia which impedes the clearance of the mucus leading to postoperative respiratory complications such as chest infection
  - impaired wound healing leading to increased risk of wound infection after surgery
  - an increase in the risk of cardiovascular complications such angina pectoris, strokes, graft failures and DVT after surgery
  - post-operative complications relating to the gastrointestinal system
  - post-operative impairment of antimicrobial and pro-inflammatory functions
  - post-operative complications relating to the musculoskeletal system such as reduction in bone fusion after fracture and operative treatment

4. Weight loss prior to routine surgery

- A Body Mass Index of 35 is considered by the CCG to be trigger for a patient's weight being a problem in terms of surgical risk and outcomes. We note that NICE uses a threshold of a BMI of 35 in recommending bariatric surgery in some individuals. We note that NHS England uses a threshold of a BMI of 30 in its policy for knee arthroplasty for armed forces personnel and their dependents.

- The CCG's position is that a BMI of 35 should trigger a requirement for weight loss. That weight loss should be five per cent or to below a BMI of 35, whichever is the lesser weight loss. Thereby balancing what is realistic for an individual patient with benefits likely to be gained.

- Procedures that are deemed to be immediately clinically necessary are exempt from the weight loss requirement. Patients whose medical condition or treatment encourage weight gain can be exempted from the weight loss requirement.

- Key considerations regarding surgical risk and obesity include:

- a nearly 12-fold increased risk of a post-operative complication after elective breast procedures[17]
- a 5-fold increased risk of surgical site infection (SSI)[18]
- an increased risk of SSI as much as 60% when undergoing major abdominal surgery[19]
- a higher incidence of SSI (up to 45%) when undergoing elective colon and rectal surgery[20]
- an increased risk of bleeding and infections after abdominal hysterectomy[21]
- a higher incidence of peri-operative deep venous thrombosis and pulmonary embolism[22]
- increased risk of complication after elective lumbar spine surgery[23, 24]
- an increased risk of restrictive pulmonary syndrome, including decreased functional residual capacity (for morbidly obese patients)[25]

- The CCG's earlier decision encompassed hip and knee arthroplasty only. That decision drew on the following rationale:

  - In February 2014, NICE updated its guidance on the management of Osteoarthritis, (NICE CG177) recommending exercise as a core treatment in the management of people with osteoarthritis who are obese and overweight

  - The NICE guidance is explicit on this point irrespective of age, comorbidity, pain severity or disability

  - NICE considers this a "strong recommendation". NICE defines a strong recommendation as,: "…when we are confident, that for a vast majority of patients, an intervention will do more good than harm, and is cost effective."26

  - Other sources cite worse outcomes associated with orthopaedic surgery where there is a high BMI[27, 28], including worse revision rates in obese patients29

  - For knee replacement, although patients make a gain with that procedure regardless of starting weight, their outcomes are lesser than with a healthier BMI. In follow-up studies, morbidly obese patients have been shown to have worse scores for pain and function into the long term along with higher revision rates30

  - This group or patients has also been shown to have higher short term risks of complications31 and can have a lesser chance of improvement32

  - The NHS England commissioning policy in respect of knee replacement in the armed forces stipulates the following conditions for funding knee arthroplasty33:

- There is evidence that conservative means have failed to alleviate pain and disability AND
- Symptoms have a substantial impact on quality of life AND
- Symptoms are refractory to non-surgical treatment AND
- The prostheses used are standard AND
- The patient is a non-smoker AND
- The patient has a BMI < 30.

- That NHS England policy also states that, "referral should be made before there is prolonged and established functional limitation and severe pain." This is also the CCG's position.

5. Restriction of second hearing aids

In deciding to restrict funding for second hearing aids for adults, the CCG considered the following research:

- Rapid Evidence Review found no large scale studies comparing one hearing aid with two[34]. Some small scale studies showing similar benefit but as many showing no benefit.

- The CCG went on to consider what might be generalisable research on the correction of hearing loss. In the case of cochlear implants, Authors from the Medical Research Council Institute of Hearing Research reports unilateral implants having the greatest gain. The unilateral QALY in 2002 was assessed at £16,744 versus no intervention, and a bilateral versus unilateral QALY of between £62k and £69k (depending on whether the second implant was given simultaneously or later.[35] This in contrast to the NICE QALY threshold for investment which is in the range £20k - £30k. Although the cost of intervention between cochlear implants and hearing aids is different, the ratio of benefit between first and second ear correction was considered to be a useful illustration.

- The CCG noted too that two hearing aids are supported by leading hearing loss groups with greater usefulness seen in dynamic and noisy situations. This consideration was influential in the decision to exempt patients with other sensory conditions or who may rely on discernment of social cues to a greater extent, such as autism with hearing loss, in order not to disproportionately impact these groups of patients.

6. Threshold for cataract surgery

- The CCG considered that DVLA standards to represent a reasonable proxy for necessity of corrected eyesight. The CCG's interim commissioning position applies the 6/12 driving standard equally to drivers and non-drivers but will also correct vision at an earlier stage of sight loss required by DVLA for some specialist vehicles.

- The CCG also notes the November 2014 Health Technology Assessment[36] from the NIHR which reviewed three Randomised Controlled Trials of clinical effectiveness, three studies of cost-effectiveness and ten studies of Health Related Quality of Life (HRQoL). The RCTs assessed visual acuity, contrast sensitivity, stereopsis and several measures of HRQoL. Improvements in binocular visual acuity and contrast sensitivity were small and unlikely to be of clinical significance. Stereopsis was improved to a clinically meaningful extent following second-eye surgery. Studies did not provide evidence that second-eye surgery significantly affected HRQoL, apart from an improvement in the mental health component of HRQoL in one RCT.

7. Restriction of ear microsuction

- The CCG noted other policies in place in the UK, bringing its policy into line with others, restricting its use to treatment of infections and anatomical abnormalities. Polices vary from allowing referral if two attempts at irrigation have been unsuccessful in primary care, coupled with hearing loss or pain, to refusing referral unless for ongoing treatment of a mastoid cavity or due to an anatomical abnormality (with exceptionality required for other funding requests). The CCG opted for parity with the most restrictive of these current UK policies.

- There is limited evidence that ear irrigation improves hearing and symptoms[37].

- Although there is consensus that ear irrigation is effective at removing wax, BMJ Clinical Evidence found no randomised controlled trials comparing ear irrigation alone to no treatment[38].

- A more recent systematic review and economic evaluation of different methods of earwax removal found the evidence on the effectiveness of different methods of irrigation or mechanical removal was equivocal[39].

- The CCG noted that the rationale for referral to secondary care following unsuccessful irrigation (or if contraindicated) is to enable the use of specialist treatments; although there are no systematic reviews or

randomized controlled trials on mechanical methods of removing earwax (other than irrigation), most Ear Nose and Throat specialists consider microsuction to be a standard treatment to enable the tympanic membrane to be seen[40].

8. Suspension of shockwave therapy

- The CCG noted that Extracorporeal Shockwave Therapy (ESWT) is not currently offered CCG-wide.
- The CCG noted the NICE appraisal of ESWT [41] [42, 43, 44] identifies that clinical outcomes are equivocal, that the procedure should be done accompanied by audit and that patients should be advised of uncertainty of outcomes.
- The CCG decision was therefore to suspend shockwave therapy for tendinopathies and bursitis. This to be accompanied by a review with secondary care to identify clinically effective and cost-effective pathways for tendonitis which may be commissioned in the future.

9. Prior approval of shoulder surgery

- The CCG noted a number of indications for shoulder surgery with equivocal outcomes compared with other treatments. Therefore it was decided to establish an Interim Commissioning Position to require prior approval for shoulder surgery with a view to developing a more comprehensive policy and commissioned pathways working with surgeons, physiotherapists, GPs and radiologists during 2015/16.
- In particular, the CCG noted the following:
    - Impingement. Little evidence from RCTs that surgical intervention is better than conservative treatments[45]
    - Frozen shoulder. Generally poor quality evidence; trials have small numbers and risk of bias. Steroid injection with physiotherapy seems to be the most effective interventions. There is limited evidence for arthrographic distension and capsular release[46, 47]
    - Shoulder replacement for OA/RA. No conservative vs operative RCTs were found but total arthroplasty thought to have better outcomes than hemiarthroplasty[48]. Follow up studies suggest that arthroplasty is associated with an improvement in pain and shoulder score (9, overall physical function improvement seems to be related to obesity, 10). The size of the improvement varies from study to study e.g. in a registry study from Denmark, mean improvement was just above the minimal clinically important difference, for total arthroplasty whereas the results for hemiarthroplasty are more equivocal[49]

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