17 Evidence based interventions (17 EBI) – where are we now? Campaigning over Treatment Access Policies.

Rationing

NHS England's (NHSE) '17 Evidence Based Interventions' (17 EBI) programme has introduced a form of rationing justified as an attempt to remove unwarranted variation in what was being made available to patients (1). This programme (considered in detail below) fails, however, to recognise and address variation caused by differing treatment access policies already developed by CCGs. In addition, CCGs are now frequently categorising interventions as being of 'low clinical value' in order to restrict patient access, even when there is a good evidence base for their use. A prime example is cataract surgery where many CCGs ignore guidance from the National Institute for Health and Care Excellence (NICE). NHS Clinical Commissioners, the national body representing CCGs describes limitations on accessing treatment as a regrettable but often unavoidable consequence of the systemic financial pressures on the health service, confirming that financial concerns are the underlying driving force for such forms of rationing. The Royal College of Ophthalmologists strongly opposes the restrictions on cataract surgery. Campaigners need to be highlighting local policies restricting access to treatment (2) as in Bristol, look carefully at whether CCG are commissioning up to the level set out by NHSE for the'17 EBI' (1) and oppose "self funding" where patients are asked to pay for treatment previously available free under the NHS (3). We should also argue against the restriction of access to beneficial interventions among the '17 EBI'.

What is the context?

As John Lister has pointed out (4) restricting treatments is gaining pace with Bristol, North Somerset and Gloucestershire listing 104 in all, with GPs no longer being able to decide when a patient should be referred for a consultant opinion. Many CCG are now restricting access to treatments of proven value such as cataract, knee and hip surgery (5,6). This is coupled with the problems of waiting times (a form of rationing) for elective surgery, as documented in a report by the National Audit Office (7):

> "The elective care waiting list is growing, and patients are increasingly waiting longer for their care. Between March 2013 and November 2018, the average number of people treated each month increased from 1.2 million to 1.3 million. In addition, the average number of patients treated within the waiting times standard for elective care increased slightly over this period. Despite, these increases, between March 2013 and November 2018, the number of people still waiting for their treatment grew from 2.7 million to 4.2 million, and the number waiting more than 18 weeks grew from 153,000 to 528,000."

and with demands for exceptional funding requests, originally used to limit cosmetic and fertility treatment, recently showing a massive increase for other interventions including hip and knee surgery as CCGs seek to limit patient access

(8). Here is a huge source of 'variation' that does not seem to trouble NHSE.

That rationing is taking place should be no surprise. The following is from an article by Stuart Player on the Socialist Health Association website (9):

> "In early 2012 the World Economic Forum considered that national healthcare systems were increasingly caught between a rock and a hard place. Fiscal crises were creating pressures to curb expenditure while it was also acknowledged that countries rely on healthcare systems for economic growth and national development. The Forum also thought there was little agreement about how to progress and "help existing models become sustainable", and set itself the task of building such a consensus.
>
> Two reports, co-scripted with McKinsey & Co, were produced . . . . As well as offering an overall diagnosis, the first report also identified various strategies and levers available to governments to resolve the above-mentioned tension. These included various forms of rationing and shifting the cost burden onto individuals and employers through, for example, mandatory private insurance, or at the other end of the spectrum, increasing tax revenue.
>
> Observers will readily recognise that the Five Year Forward View of October 2014, which STPs are now set to implement, is drawn directly from the World Economic Forum's diagnosis of the healthcare crisis, and also reproduces the Forum's prescription for supply-side change and the various levers available to policy makers."

In the WEF report, rationing as one of the options open to government in addressing rising healthcare costs is presented in the following way: (The financial stability of healthcare systems – a case for change. World Economic Forum 2012 (10):

> "The bluntest approach is to ration access to care. This would imply either narrowing the population covered, for example, restricting coverage; imposing cash-limited budgets and allowing waiting lists to rise; or reducing the scope of services covered through a smaller benefits package".

The report also highlights a dilemma for those imposing rationing:

> "Extreme forms of rationing, however, could have the reverse effect: untreated conditions may worsen during waiting periods, increasing the total cost of care; and more individuals would likely seek costly emergency care rather than less-expensive preventative treatment. In its extreme form, rationing is unpalatable and undesirable. However, with increasing access to data, a growing understanding of which interventions have the best outcomes and returns should allow definitions of minimum standards in an increasing range of areas."

The WEF report was produced in association with McKinsey and Company, who in February 2009 were instructed by the Department of Health to provide advice on:

> "how commissioners might achieve world class NHS productivity to inform the second year of the world class commissioning assurance system and future commissioner development".

Their thoughts are available as a pdf version of a PowerPoint presentation (11). Slides 51 & 52 deal with the potential for savings through decommissioning of procedures of 'limited clinical benefit'. These are now surprisingly familiar, and include: tonsillectomy, back pain, grommets, trigger finger, Dupuytren's, knee washouts, D&C, minor skin surgery, aesthetic surgery of various types, knee surgery, hip surgery, cataract removal – most of these now appearing among both the '17 EBI' (1) and the shopping lists for "self funding" patients (12). Prior to this, in 2007, a focus on 'variation' by the London Health Observatory (one of nine regional Public Health Observatories in England set up in 2001 by the Department of Health, now defunct and amalgamated into Public Health England in 2013) estimated potential savings from standardising treatment access criteria (13).

The aim had been:

> "to estimate the potential savings that could be reinvested in London if each London PCT adopted the same access criteria to a selected list of 34 hospital based procedures" (the 'Croyden list')(13).

Hysterectomy was the 10th most common procedure on the Croydon list, and a suggested recommendation to commissioners was that:

> "Hysterectomy for heavy menstrual bleeding will only be funded after a trial with intrauterine levonorgestrel has not relieved symptoms or is contraindicated; or other effective treatments have failed in line with NICE guidelines".

although this was in fact an over interpretation of NICE guidance (see below). The authors considered that variation in hospital clinical practice was likely to be as important as variation in primary care referral practice in accounting for different rates of interventions and pointed out that the assumptions about savings were based on value judgements.

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NHSE and '17 Evidence Based Interventions' (consultation July 2018; statutory guidance November 2019)

This programme is discussed in detail below, but the main impact of the NHSE recommendations coming from this exercise relates to procedures that might be regarded as purely 'cosmetic' and where there are no associated physical complications, i.e. removal of benign skin lesions, removal of ganglion, and breast reduction surgery. However, there is likely to be a much wider impact through

how CCGs interpret NHSE guidance, discouraging GPs from making referrals for treatment, and patients being told (wrongly): "the NHS does not do that any more"(unless of course you are willing to pay a private providers or for "self funding"). It is crucial for campaigners to examine local CCG commissioning policies to see if they are failing to provide services for patients who would actually meet the treatment criteria set out by NHSE (1).

Many CCGs are also extending the list of conditions regarded as 'of limited clinical value', and are prepared to ignore NICE guidance (a prime example being cataract surgery). NHSE, too, wish to increase the scope of their work on 'evidence based interventions':

> "We will first develop proof of concept, by having a relatively narrow initial focus on a few interventions, rather than pursuing all possible opportunities at once. One of the reasons similar initiatives have failed in the past is because they aimed too wide too soon" (14).

In addition, by encouraging hospitals to raise money through private work, we are now seeing hospitals offering restricted treatments (many on both the McKinsey and the '17 EBI' lists) or those with long NHS waiting times, to patients willing to pay – so called "self funding" patients. This was first highlighted in the British Medical Journal in 2012 (3). More recently it has come to light at Warrington and Halton Hospitals NHS Foundation Trust where it is called 'My Choice' (12). Nothing could more clearly demonstrate the direction of travel in the NHS, where patients who have been denied NHS procedures including hip and knee replacements, cataract and tonsil removals, breast enlargements and reductions, are able to have them at a price if they have the money. As the Chief Executive at Warrington tellingly commented: "Procedures of low clinical priority do not mean low value to our patients, and we are pleased to be able to make a large number available at a really affordable price at their local hospitals and by our most trusted NHS staff. 'My Choice' is by the NHS, for the NHS" (12).

Points that campaigners should raise with commissioners

- NHSE make much of 'Evidence Based Medicine', but this has been defined as: "The conscientious explicit and judicious use of current best evidence in making decisions about the care of individual patients". It is therefore something that is done in individual interactions between patient and clinician and not imposed through bureaucratic means or financial levers, as the '17 EBI' programme seeks to do.
- NHSE explains its EBI programme (EBI consultation document, p10, point 5) as "being driven by new national ambitions to embed personalised care across England, so that shared decision making between patients and clinicians becomes the norm", while at the same time taking decision making away from doctors.
- the context is clearly a drive to reduce health care expenditure (see below)

- although the category 1 (see below) interventions are largely unnecessary, category 2 interventions clearly have value; while NHSE claim they were chosen because of wide variation due to the NHS not following established recommendations - smoothing out variation in existing commissioning policy should allow for increases as well as decreases in interventions being performed, and not a universal reduction (as evidently anticipated by NHSE given their published predicted activity figures)
- the category 2 interventions in fact are largely taken from management consultants McKinsey's 2009 presentation to the Department of Health on cost saving (see below), and the 'Croydon list' of 2007
- NHSE badge the '17 EBI' programme as being a joint venture with Royal Colleges and with NICE, implying their approval of the guidance given to CCGs; NICE and (to a certain extent) the Royal College of Physicians refute this
- the term 'evidence based' interventions is a misnomer, since for some very common procedures such as removal of benign skin lesions there is no evidence base; this does not mean there is no value, and patients views on what matters to them should always be sought
- NHSE implies that its recommendations are consistent with NICE guidance, however, for five interventions there was no NICE guidance; in one there is some conflict with NICE (snoring), and for another (breast reduction) conflict with a specialist society commissioning recommendations
- NHSE have anticipated the recommendations of a NICE clinical guideline currently under development on interventions for snoring
- NHSE have anticipated the outcome of a clinical trial (tonsillectomy)
- guidance developed by professional societies using NICE accredited methodology is not equivalent to a NICE guideline and should not be presented as being endorsed by NICE
- where hospitals are encouraging "self funding" patients, who decides what treatments are on offer and on what basis?
- are any "self funded" treatments on offer in accord with national guidelines and national screening protocols?
- GPs should be able to refer a patient to a specialist if they consider that they need an intervention; it is then for the specialist to advise about whether the intervention is available (i.e. the patient meets the necessary criteria; GPs should not have to interpret NHSE guidance and decide themselves against making a specialist referral)
- do local commissioning arrangement actually meet NHSE recommendations in terms of who should be eligible for an intervention (i.e. are there services for patients who meet the NHSE '17 EBI' treatment criteria, or are the CCG ignoring these)?

Questions to ask and points to make when CCG propose limiting access to other treatments on the basis of "addressing variation":

- are there current clinical guidelines (NICE, or others) that cover these

treatments (e.g. cataract surgery and NICE guidance)?

- will you be compliant with these and if not, why not?
- if no guideline, how has the decision to change access been made (i.e. what is the evidence base that has been considered)?
- where variation exists, the aim should be to bring everyone up to the highest standard rather than down to the lowest?
- where variation is reduced, some providers ('under performers') will need to do more and some ('over performers') less than they did before; have you identified likely impact in different areas?
- what value do patients themselves attach to the intervention?
- will these threatened treatments never the less be available to "self funding" patients?

'17 Evidence Based Interventions' programme

After a consultation on 17 interventions, NHSE published statutory guidance for CCGs that has been widely adopted. These set out the criteria under which treatments should be made available (1).

According to NHSE this was done to address variation in how frequently these procedures were performed in different areas in order to reduce ineffective interventions and thereby reduce harm to patients, free up professionals' time, help keep doctors up to date, encourage innovation, maximise value and avoid waste. The interventions were divided into two categories:

Category 1 interventions - should not be routinely commissioned, with patients only to have access if a successful Individual Funding Request is made on their behalf:

1. Snoring surgery (in the absence of obstructive sleep apnoea)
2. Dilatation and curettage for heavy menstrual bleeding
3. Knee arthroscopy for patient with osteoarthritis
4. Injections for nonspecific low back pain (without sciatica)

Category 2 interventions - should only be commissioned or performed when specific criteria are met:

1. Breast reduction
2. Removal of benign skin lesions
3. Grommets for glue ear in children
4. Tonsillectomy for recurrent tonsillitis
5. Haemorrhoid surgery
6. Hysterectomy for heavy menstrual bleeding
7. Chalazia removal
8. Arthroscopic shoulder decompression for subacromial shoulder pain
9. Carpal tunnel syndrome release
10. Dupuytren's contracture release
11. Ganglion excision

12. Trigger finger release
13. Varicose vein surgery

The focus was said to be on interventions commissioned by CCGs where there was high variability in application of clinical guidelines. In other words, it was implied that there were existing clinical guidelines that were not being followed. Page 9 of the consultation document (15) asserts:

> "The National Institute for Health and Care Excellence (NICE) and Choosing Wisely UK have published important guidance to try to eliminate ineffective practice, but the NHS has not consistently implemented their recommendations".

Supporting references for this statement comprise NICE's 'do not do' recommendations (16) which does not include any of the 17 EBI, and 'Choosing Wisely' (17) which only briefly touches on one of the interventions: carpal tunnel syndrome. While not specifying whether commissioners were failing to follow guidance (i.e. not providing treatments known to work, or providing treatments known not to work), at a public consultation held by NHSE in Leeds it was stated that the problem was in fact due to doctors not following accepted guidelines. The aim was therefore to come up with an agreed set of criteria for category 2 treatments, and to virtually put an end to category 1 interventions through economic levers.

Of course, this cuts both ways: if guidelines are not being followed there may be either over or under provision of services depending on where you live. Logically therefore, by NHSE introducing a national standardised set of criteria for when treatment is appropriate, increased activity in some areas and decreased activity in others might be expected. NHSE came up with projected changes in activity for each intervention in each individual CCG, but puzzlingly indicated almost always a reduction (or no change) in activity, and never an increase.

In fact, one very important explanation for variation can be found in pre-existing treatment access policies developed first by some primary care trusts (PCT) and then CCGs. Breast reduction surgery features on the list of '17 EBI' and is a case in point: visit the NHS website (18) and it states:

> "Some CCGs do not fund breast reduction surgery at all, and others fund it selectively if you fulfil certain criteria".

Who is not following guidelines? – commissioners or doctors? It is not clear whether NHSE looked carefully at such pre-existing access policies as a cause of variation, but presumably those CCGs who were not offering breast reduction surgery at all should now be expected to do so, in line with the NHSE criteria in their new guidance (1)?

The Royal College of Surgeons had previously been severely critical of earlier attempts by PCT to restrict treatments by classifying them as 'procedures of limited value' (19) denouncing these because: "the concept has been extended because of the current financial restrictions, and many proven operations known

to enhance health and improve quality of life have been included in this category, and hence are being denied to patients who need them". Such a criticism can also be levelled at the '17 EBI' programme while the real world outcomes of this are now being demonstrated in "self funding" initiatives (3,12).

Changes post '17 EBI' national consultation

Following the national consultation on '17 EBI' there were some minor changes made to treatment criteria. These included expanding the recommendation wording for carpal tunnel syndrome, Dupuytren's contracture release, ganglion excision and trigger finger release to align with proposals from the British Society of the Hand. In addition, children were excluded from the criteria related to Dupuytren's contracture release, trigger finger release and snoring surgery as these conditions present differently in children and may indicate more serious underlying conditions. Clarification was also given that children who cannot undergo normal assessments were still able to access specialist advice for glue ear.

Commissioning implications

CCGs are expected to comply with the NHSE guidance on '17 EBI':
"We are mandating compliance to the Evidence-Based Interventions programme through the NHS Standard Contract."

"The Provider must manage Referrals and provide the Services in accordance with the Evidence-Based Interventions Policy."

"If the Provider carries out a Category 1 Intervention without evidence of appropriate prior approval having been granted by the relevant Commissioner, or a Category 2 Intervention other than in accordance with the Evidence-Based Interventions Policy, the relevant Commissioner will not be liable to pay for that Intervention."

Note that the NHSE focus is only on CCGs who might be commissioning interventions for patients who do not meet NHSE indications, but apparently leave CCGs free to choose not to commission interventions for patients who do meet these indications. This is one of the clearest indications that the fig leaf of 'evidence based medicine' is being used to cover up rationing.

What do NHSE think might happen when CCGs adopt their new criteria?

Currently there are 17,650 Category 1 interventions performed each year (75% of which are injections for nonspecific low back pain without sciatica; 19% knee arthroscopy with osteoarthritis; 5% interventions from snoring without sleep apnoea; 1% D&C for heavy menstrual bleeding). It is expected that these Category 1 interventions will fall to almost zero.

There are 317,376 Category 2 interventions performed each year, removal of benign skin lesions representing 36% of these, and together with carpal tunnel

release and tonsillectomy (the next two most common interventions) accounting for 60% of all category 2 interventions.

Category 2 interventions are expected to be reduced to the 25th percentile of the age-sex standardised rate of CCGs. This means an overall expected percentage reduction in numbers of procedures as follows:

- breast reduction 35%
- removal of benign skin lesions 40%
- insertion of grommets 38%
- tonsillectomy 33%
- haemorrhoid surgery 33%
- hysterectomy for heavy menstrual bleeding 24%
- chalazia removal 72%
- shoulder decompression 49%
- carpal tunnel release 34%
- Dupuytren's contracture release 29%
- ganglion excision 41%
- trigger finger release 33%
- varicose vein surgery 30%

As stated above however, the possibility that activity will increase in some CCGs does not seem to have been recognized in the activity projections published by NHSE (1). Commenting on this point and contradicting these figures, in reply to a letter from myself, NHSE stated: "We aim to reduce variation, and recognise that this may mean an increase in some cases".

The most common intervention is removal of a benign skin lesion, accounting for over one third of Category 2 procedures. There is no NICE guidance for this. It seems likely that in the majority of cases these would be things like moles that a dermatologist could confidently identify as non-malignant on clinical examination, and were removed for cosmetic reasons (i.e. psychological distress). There is, however, no breakdown of just what diagnoses make up the 116,255 'benign skin lesions' removed in 2017/18 or of why patients wished them to be removed and whether they felt benefit as a result. Note, that the guidance does not apply to removal of a lesion where there is any concern of malignancy, or any uncertainty about this, as there is a NICE guideline for suspected malignancy. 'Benign' can clearly include disfiguring lesions; removal of these is an important element in training of dermatologists.

Are NICE and the Royal Colleges fully on board with NHSE commissioning advice?

NHSE states that their guidance has been developed "in partnership with NHS Clinical Commissioners, the Academy of Medical Royal Colleges, NHS Improvement and the National Institute for Health and Care Excellence" (NICE). In addition: "all of the clinical criteria consulted on were developed directly from existing NICE, NICE-accredited or specialist society guidance and local CCG

policies, and the final set of wording used has been checked by the relevant Royal Colleges, specialist societies, individual specialists, as well as clinical experts from within NHS England."

NICE is the organisation par excellence that produces clinical guidelines for health professionals in the UK, through a well established and transparent process. I asked NICE, the Academy of Medical Royal Colleges (AoMRC) and the Royal College of Physicians (RCP) by letter if they thought robust processes had been followed in the consultation and the subsequent development of guidance:

1. Do you consider that the NHSE process of consultation and response/recommendations has been carried out to the very high standards that underpin NICE guideline development?
2. Do you endorse the content of the consultation response including the recommendations for commissioning?
3. NHSE intends "to make this a much wider ongoing programme"; will NICE continue to endorse this process or seek modifications that would ensure alignment with established NICE guidance and procedures?

The AoMRC expressed full support for the consultation process and subsequent commissioning guidance, seeing it as fitting very much with their 'Choosing Wisely' initiative (www.choosingwisely.co.uk/about-choosing-wisely-uk/). Professor MacEwen, chair of the AoMRC insisted that the '17 EBI' consultation is

> "entirely focused on improving outcomes and ensuring doctors and patients take a shared approach to decision making", (unless perhaps their shared decision conflicts with NHSE guidance? - JP).

The Royal College of Physicians (RCP) had relatively few concerns, but stated it had raised issues over criteria for carpal tunnel decompression on behalf of the 'British Society for Clinical Neurophysiology' and the 'Association of British Neurologists'. Furthermore, at no time did the College formally endorse the '17 EBI' programme, going so far to say that to state it had been developed in collaboration with the Royal Colleges "could be misinterpreted". NHSE guidance reports that: "the final set of wording used has been *checked* by the relevant Royal Colleges" but does not say whether the Colleges gave approval.

The opinion of the RCP in November 2018 was that the response to the '17 EBI' consultation should "not be published in its current state"; (it was in fact published on 28th November). A subsequent letter from the RCP in March 2019 indicates that discussions with NHSE (about carpal tunnel guidance) were ongoing. Curiously, the British Association of Dermatologists did not make any representations via the RCP over benign skin lesions being a major target for reducing activity, and have apparently endorsed the new clinical criteria set out by NHSE.

The NICE response was slow to come and required some chasing up, but was revealing:

> "This work was undertaken by NHS England rather than NICE. It would be inappropriate for us to comment on the validity of this work and the subsequent published guidance."

Given the extensive and prominent references to NICE in the NHSE document, which was signed off by Prof. Gillian Leng, deputy CEO and director of health and social care for NICE, this statement is puzzling. There is, however, a fundamental contradiction between the approach of NHSE ('we will apply financial levers to stop you doing interventions') and that of NICE: "When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual".

How much of a barrier to treatment might the NHSE guidelines be?

Below, I consider each intervention in turn, comparing NHSE treatment criteria with NICE guidance (when available) or other accepted guidance. Bear in mind that CCGs may well interpret NHSE guidance more strictly than the criteria taken at face value.

Category 1 interventions:

A) snoring surgery: there is no NICE guidance on snoring surgery at present, but some is due in August 2020. Currently there is NICE 'interventional procedure guidance' covering radiofrequency ablation of the palate (20), one of the interventions for snoring. This does not say whether this treatment should be made available, but does recognize that there is short term evidence of efficacy and that, if it is used, normal arrangements for surgery should apply. When asked about this guidance not being referred to, NHSE replied:

> "The NICE guidance on radiofrequency ablation . . . . are outside the scope of the guidance".

However, the '17 EBI' consultation document seems to contradict this by stating that:

> "This guidance relates to surgical procedures . . . (including) . . . . radiofrequency ablation of the palate".

NHSE guidance therefore appears to be more restrictive than NICE.

B) D&C for heavy menstrual bleeding (HMB): NICE guidance (21) does not regard D&C as appropriate for investigation or treatment of HMB, and therefore NHSE guidance is not in conflict with NICE over this intervention.

C) Knee arthroscopy for patients with osteoarthritis: NICE guidance (22) states:

> "Current evidence suggests that arthroscopic knee washout alone should not be used as a treatment for osteoarthritis because it cannot demonstrate clinically useful benefit in the short or long term".

In addition:

> "Referral for arthroscopic lavage and debridement should not be offered as part of treatment for osteoarthritis, unless the person has knee osteoarthritis with a clear history of mechanical locking (not gelling, 'giving way' or X-ray evidence of loose bodies)".

NHSE guidance now includes:

> "Referral for arthroscopic lavage and debridement should not be offered as part of treatment for osteoarthritis, unless the person has knee osteoarthritis with a clear history of mechanical locking."

There is therefore no conflict between NHSE and NICE over arthroscopic knee washout.

D) Injections for non-specific low back pain: NHSE agrees with NICE guidance.

Category 2 interventions: only routinely commissioned or offered when specific criteria are met -

E) Breast reduction: there is no NICE guidance. There is a commissioning guide (23) from the British Association of Reconstructive and Aesthetic Surgery who under the aegis of the Royal College of Surgeons (RCS) published commissioning advice in 2014 stating that in addition to general criteria being fulfilled, "emotionally and socially bothered by having large breasts", and "low self esteem and depression" could be indications for surgery. The surgeons comment that:

> "Breast reduction improves the quality of life of patients by amelioration of associated physical symptoms. The patient is not likely to present with further physical symptoms. There is also an improvement in the patient's psychological wellbeing, self-esteem, willingness to engage in social activities and employment potential."

NHSE proposes criteria, all of which must be met, before the NHS will provide breast reduction for women, but no psychosocial criteria are mentioned. NICE refers to the different criteria from Royal College of Surgeons including:

> "Have some or all of the following signs and symptoms:
> - Emotionally and socially bothered by having large breasts
> - Low self-esteem and depression
> - Breast size limits physical activity
> - Back, neck and shoulder pain caused by the weight of breasts"

While the current NHSE guidance to CCG recognises that breast reduction surgery can improve quality of life and reduce anxiety and depression, it sees its primary role as relief of physical symptoms. The NHSE criteria reject psychological indications and insist on a list of 8 criteria being met prior to surgery, and are therefore more restrictive than the RCS commissioning guidance.

When questioned about this, the response from NICE was:

> "I can confirm that we have not been asked to develop any specific guidance on breast reduction surgery. The NICE Accreditation programme assesses the processes used by external organisations to produce guidance and advice. The aim of the programme is to help raise standards in guidance production. However NICE Accreditation is not the same as an endorsement of the recommendations in the guidance itself and it does not mean that advice published by organisations accredited by NICE is considered to be NICE guidance. Instead it is an acknowledgement of the robust and high quality processes used to develop it."

The response from NHSE was:

> "During the development of the EBI guidance there was a lot of debate about this point with specialist clinicians. While it is recognised that breast hyperplasia impacts on psychological health it was determined, by mental health experts, GPs, breast surgeons, and patients that it is not appropriate to offer surgery as a treatment for psychological distress. Many concerns were raised about the impact of this potential recommendation on women with body dysmorphia and potential wrong treatment. We concluded that the care by the GP to support the woman through the decision would include a psychological aspect. We concluded that the criteria were broad enough and fair to ensure that women with breast hyperplasia would not be prevented from accessing surgery".

This implies the surgeons had changed their minds on psychological indications (which seems unlikely). It is also unclear how "the decision would include a psychological aspect" when the NHSE criteria reject psychological indications and insist on 8 criteria being met prior to surgery.

F) Removal of benign skin lesions: there is no NICE guidance. NHSE advise that benign lesions have to be causing some other problem (like bleeding) to warrant removal (except for facial warts, and prominent blood vessels in children). It is difficult to know what the benign skin lesions being removed actually are (in terms of specific diagnosis), but clearly patients have felt strongly enough about them to want them removed and a GP/surgeon has endorsed this wish. NHSE states that:

> "there is little evidence that removing benign skin lesions to improve appearance is beneficial",

but begs the question - 'have you asked the patients?', and invites the comment – 'absence of evidence is not evidence of absence'. The NHSE recommendations for benign skin lesions are clearly aimed at restricting access to surgical removal.

NICE commented to me:

> "We cannot comment on guidance published by other organisations (such as NHS England) nor can we comment on concerns about the number of procedures that have been performed. We do not have a role in specifying or monitoring the delivery of local NHS services or the expenditure of local NHS budgets."

G) Grommets for glue ear in children: NHSE recommendations agree with NICE.

H) Tonsillectomy for recurrent Tonsillitis: there is no NICE guidance. The NHSE guidance states:

> "It is important to note that a national randomised control trial is underway comparing surgery versus conservative management for recurrent tonsillitis in adults which may warrant review of this guidance in the near future".

The criteria from NHSE fit with those in the Scottish Intercollegiate Guidelines Network (SIGN) national clinical guideline, and therefore are not restrictive. There is a 'clinical knowledge summary' for sore throat by NICE (24), which states:

> "For people with severe recurrent tonsillitis (a frequency of more than 7 episodes per year for one year, 5 per year for 2 years, or 3 per year for 3 years, and for whom there is no other explanation for the recurrent symptoms), referral to an ear, nose, and throat specialist is advised as this cohort may benefit from tonsillectomy".

NICE bases this advice on the SIGN guideline. The NHSE recommendations are not restrictive.

I) Haemorrhoid surgery: there is no NICE guideline, although there is a NICE clinical knowledge summary (CKS) (25) that recommends referral to secondary care for further investigation and management for:

> "People who do not respond to conservative treatment", and "People with recurrent symptoms who do not respond to primary care management".

NHSE recommends that:

> "many patients will respond to outpatient treatment in the form of banding or perhaps injection. Surgical treatment should only be

> considered for those that do not respond to these non-operative measures or if the haemorrhoids are more severe, specifically: Recurrent grade 3 or grade 4 combined internal/external haemorrhoids with persistent pain or bleeding; or, irreducible and large external haemorrhoids. In cases where there is significant rectal bleeding the patient should be examined internally by a specialist".

The Association of Coloproctologists of Great Britain and Ireland have approved the NHSE recommendation and criteria. The criteria do not appear restrictive and the NHSE recommendation on haemorrhoid surgery does not conflict with the NICE CKS.

J) Hysterectomy for Heavy Menstrual Bleeding (HMB): there is NICE guidance (26). NHSE recommends that:

> "It is important that healthcare professionals understand what matters most to each woman and support her personal priorities and choices. Hysterectomy should be considered only when: other treatment options have failed, are contradicted; there is a wish for amenorrhoea (no periods); the woman (who has been fully informed) requests it; the woman no longer wishes to retain her uterus and fertility".

It therefore should leave the door open to go directly to hysterectomy if that is what the patient wants, but because the wording may be considered ambiguous, I requested clarification from NHSE:

> "I would be grateful for clarification regarding interpretation of the following paragraph from the "Evidence based interventions: guidance for CCGs", p30: "Hysterectomy should be considered only when: other treatment options have failed, are contradicted; there is a wish for amenorrhoea (no periods); the woman (who has been fully informed) requests it; the woman no longer wishes to retain her uterus and fertility. I take this to mean that hysterectomy could be considered in any one of the following situations:
> a) other treatment options have failed, are contradicted
> b) there is a wish for amenorrhoea (no periods)
> c) the woman (who has been fully informed) requests it
> d) the woman no longer wishes to retain her uterus and fertility - rather than meaning that all four of these criteria would have to be met before considering hysterectomy.

and received the following reply from NHSE:

> "Regarding your most request for clarification of page 30 of the guidance, it applies when a patient meets one of the four criteria listed rather than having to meet all four. Please refer to NICE guidance for a full explanation."

The wording by NHSE in its recommendations to CCGs is clearly open to various

interpretations. For commissioners who might think otherwise, NICE guidelines NG88 (26) do indeed explicitly permit hysterectomy as a treatment for HMB with fibroids >= 3cm diameter without other treatments having first to fail or be contradicted.

In addition, NICE guidelines always give leeway to clinicians and include the following statement:

> "The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. **When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual**, in consultation with them and their families and carers or guardian."

K) Chalazia removal: there is no NICE guidance, but there is a NICE clinical knowledge summary. There is no conflict between NHSE and NICE over criteria for chalazia removal.

L) Arthroscopic shoulder decompression: there is no NICE guidance. The guidance produced by the British Elbow and Shoulder Society (developed through a process accredited by NICE) is fully referenced by NHSE. This states that:

> "Surgery is indicated for persistent or significant pain and loss of function despite appropriate non-operative treatment".

The British Orthopaedic Association and the British Elbow and Shoulder Society have approved the NHSE recommendations and clinical criteria. The recommendation does not appear more restrictive.

M) Carpal Tunnel: there is no NICE clinical guideline; there is a NICE 'scenario: management of carpal tunnel syndrome' document but no guideline on management (27). This makes it clear that if symptoms are severe or functional ability is reduced a patient should be referred to a specialist. NHSE recommends:

> "in refractory (keeps coming back) or severe cases surgery (good evidence of excellent clinical effectiveness and long term benefit) should be considered".

The British Society for Surgery of the Hand approved the NHSE recommendations and clinical criteria. Objections that I am told were raised by the Royal College of Physicians are not mentioned. The NHSE recommendation does not appear restrictive and is not in conflict with NICE.

N) Dupuytren's Contracture release in adults: there is no NICE guideline. There is

a NICE clinical scenario (28) that states:

> "For people with Dupuytren's contracture and/or significant loss of function - refer to a hand surgeon, or a specialist in plastic or orthopaedic surgery, for surgical management".

However, under treatments in secondary care (linked to "surgical management") it also lists enzyme injection therapy. NHSE recommendations state:

> "An intervention (collagenase injections, needle fasciotomy, fasciectomy and dermofasciectomy) should be considered".

There is therefore no conflict between NHSE and NICE guidance on management of Dupuytren's contracture.

O) Ganglion excision: NICE does not have guidance on ganglion excision. NHSE advise:

> " no treatment unless causing pain or tingling/numbness or concern (worried it is a cancer)".

The British Society for Surgery of the Hand approved the NHSE recommendations and clinical criteria. This is likely to restrict excision for cosmetic reasons. NHSE commented to me as follows:

> "With ganglion, this resolves usually spontaneously over time but the criteria allow for removal if there is concern."

In fact, according to the literature only about 50% resolve spontaneously (and some do recur after surgery).

P) Trigger finger release in adults: NICE does not have a guideline on trigger finger, therefore there is no conflict with NHSE recommendations. Guidance from the British Society for Surgery of the Hand was produced in a process accredited by NICE, and is now included by NHSE. It is stated that The British Society for Surgery of the Hand approved the changes to the recommendations and clinical criteria; these do not appear restrictive.

Q) Varicose Veins: there is NICE guidance (29). The NHSE guidance states:

> "For patients whose veins are purely cosmetic and are not associated with any symptoms do not refer for NHS treatment".

This is consistent with NICE guidance, since this only applies to patients with symptomatic varicose veins or those with additional physical findings (e.g. skin changes). However, The full NICE guideline includes the following re cosmetic impact:

> "Whilst the GDG [Guidance Development Group] were keen to not be seen

> to make a recommendation about cosmetic surgery on the NHS, they were apprehensive about making a judgement on the impact of cosmetic concerns on the individual. They felt that the impact that symptomatic varicose veins has on the quality of a patient's life should be explored individually when deciding the best course of action."

For NHSE, if there were additional physical findings, this by definition would not be a 'purely cosmetic' problem, and referral should ensue to a vascular service.

NHSE advice not to refer patients who have no symptoms is consistent with NICE. NICE refers to compression hosiery in someone who has had an intervention for varicose veins as part of their post-intervention management, but says:

> "Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable".

NHSE states that if you are someone suitable for interventional treatment, don't use compression hosiery before this is done (in other words, go straight for an effective intervention). NHSE also says:

> "Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable".

There is therefore no conflict between current NHSE recommendations and those of NICE with regard to treatment of varicose veins, although NICE recommends that the quality of a patient's life should be explored individually when deciding the best course of action.

Summary on the '17 EBI'

Is NHSE guidance to commissioners restrictive, i.e. if its criteria have to be met will this inevitably reduce access to some interventions compared with NICE or other accepted guideline?

- NHSE disregards NICE content of an interventional procedure guidance technology with regard to the utility of radiofrequency ablation of the soft palate for snoring, and is therefore restrictive.
- NHSE guidance is not in conflict with NICE over D&C.
- NHSE guidance is not in conflict with NICE over arthroscopic knee washout.
- NHSE guidance is not in conflict with NICE over injections for low back pain.
- NHSE guidance is not in conflict with NICE over breast reduction surgery (as there is no NICE guidance), but does conflict with the guidance from the Royal College of Surgeons and is therefore restrictive.
- NHSE guidance on removal of benign skin lesions is not in conflict with NICE (as there is no NICE guidance). There is no national guideline on 'benign skin lesions', but the NHSE guidance is clearly meant to be

restrictive, and will have an adverse affect on training.

- NHSE guidance is not in conflict with NICE over grommets.
- NHSE guidance is not in conflict with NICE over tonsillectomy for recurrent tonsillitis (and is consistent with SIGN guidance) but pre-empts the outcome of a current trial.
- NHSE guidance is not in conflict with NICE over haemorrhoid surgery.
- NHSE guidance is not in conflict with NICE over hysterectomy for heavy menstrual bleeding, although the wording of the published guidance is open to misinterpretation by CCG and referring clinicians.
- NHSE guidance is not in conflict with NICE over chalazia removal.
- NHSE guidance is not in conflict with NICE over arthroscopic shoulder decompression, as there is no NICE guidance. NHSE guidance does not appear restrictive.
- NHSE guidance is not in conflict with NICE over carpal tunnel syndrome.
- NHSE guidance is not in conflict with NICE over Dupuytren's contracture.
- NHSE guidance is not in conflict with NICE over ganglion excision as there is no NICE guidance on this issue; it does appear restrictive however.
- NHSE guidance is not in conflict with NICE over trigger finger (NICE has no guidance on this matter) and does not appear restrictive.
- NHSE guidance is not in conflict with NICE over treatment of varicose veins, although NICE recommends that the quality of a patient's life should be explored individually when deciding the best course of action.

Given the above, a significant problem will be how commissioners interpret NHSE guidance and the fact that they will be able to set their own more restrictive indications for interventions. This is a crucial area for NHS campaigners to explore locally, together with treatment access policies for hip, knee, cataract surgery etc. and any "self funding" schemes.

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There is an alphabetical list of conditions; click on the condition and a summary of relevant NICE publications appears.

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