Engagement Report for Clinical Commissioning Policies

Unique Reference Number	1674
Policy Title	Surgical correction for Pectus Deformities
Accountable Commissioner	Nigel Andrews
Clinical Reference Group	Specialised Cancer Surgery CRG
Which stakeholders were contacted to be involved in policy development?	A policy working group was established in line with NHS England's standard methods. The draft policy proposition was sent to the following groups for comment: • Specialised Cancer Surgery Clinical Reference Group (CRG) • Registered stakeholders of the Specialised Cancer Surgery CRG • Specialised Respiratory CRG • Paediatric Surgery CRG Registered stakeholders of the cancer surgery CRG
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been involved	Society for Cardiothoracic Surgery in GB and Ireland – the Society is a registered stakeholder for the Specialised Cancer Surgery CRG and were invited to comment as part of stakeholder testing.
Which stakeholders have actually been involved?	Feedback on the draft policy proposition was received from: • Society for Cardiothoracic Surgery in GB and Ireland In addition, individual responses were received from members of:

	• Specialised Cancer Surgery CRG • Specialised Respiratory CRG
Explain reason if there is any difference from previous question	Not applicable.
Identify any particular stakeholder organisations that may be key to the policy development that you have approached that have yet to be engaged. Indicate why?	None identified.
How have stakeholders been involved? What engagement methods have been used?	The draft policy proposition was distributed to stakeholders via email for a period of two weeks of stakeholder testing, in preparation for public consultation. Stakeholders were asked to submit their responses via email, using a standard response and in line with NHS England's standard processes for developing clinical commissioning policies. Stakeholder testing asked the following questions: • It is proposed that highly specialised products will go for period of public consultation. Please select the consultation level that you consider to be most appropriate. (6 weeks or up to 12 weeks) • Do you have any further comments on the proposed changes to the document? • If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial 'sense check'. • Please declare any conflict of interests relating to this document or service area.
What has happened or changed as a result of their	Five responses were received to stakeholder testing. All comments were noted but no changes to the policy proposition have been made as a result of stakeholder feedback.

input?	One respondent fully supported the policy and the non-routine commissioning position. The remaining four respondents agreed that the current available evidence did support the routine commissioning of surgery for pectus deformities, however felt that based on their clinical knowledge, there were a sub-group of patients that did benefit from surgery both clinically and psychologically. These respondents recommended: • Allowing a particular sub-set of patients to continue to access treatment through setting a degree of severity which would make the surgery justifiable. • Allowing surgery to be commissioned from a select number of centres with prospective registry entry to monitor outcomes. • Considering evaluating this surgical intervention through the Commissioning through Evaluation (CtE) process to allow patients to continue to access treatment and assess impact. It should be noted that outcomes depending on the severity of deformity were considered as part of policy development but no evidence was found to demonstrate that certain sub-groups have improvements in clinical and psychological outcomes.
How are stakeholders being kept informed of progress with policy development as a result of their input?	All stakeholders (including CRG members and registered stakeholders) will be notified when the draft policy proposition goes out to public consultation.
What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement?	There were 5 responders to the stakeholder feedback, 2 did not respond to this question, 2 recommended 12 weeks and 1 recommended 6 weeks It is recommended that the policy proposition is subject to 12 weeks of public consultation.

Appendix 1 - Stakeholder/CRG Feedback

Organisation Responding	Feedback Received	PWG response	Resulting Action
Blacon Health and Wellbeing Group	In the plain English section the terms Scoliosis, Marfans Syndrome and Ehlers -Danlos Syndrome were not explained what they are although they were explained a lot further down the document . I fully agree that this should not be routinely commissioned and wonder why it is included in a Cancer CRG when there is no connection to Cancer in the policy	Support for the policy proposition noted.	No action required.
Society for Cardiothoracic Surgery in GB and Ireland	Severe pectus deformities are uncommon, but can cause very significant symptoms and distress to patients who suffer from them. Less than 400 operations to correct pectus deformities are performed in the UK each year and so meaningful statistical analysis of patient cohorts is difficult. Despite the lack of robust RCT evidence we strongly believe that the majority of patients with severe deformity do benefit from surgery and that both open and minimal access (MIRPE/ Nuss) operations should be available in centres that have appropriate expertise. Although the deformities are rarely a cause of physical disability, given that they manifest in children and teenagers the psychological trauma can be immense in this vulnerable group of patients. The SCTS believes that operations to correct pectus deformities are extremely helpful in relieving the psychological effects of the problem, despite the lack of supportive evidence in the literature	Comments noted. No evidence was found in the literature to support improvements in psychological outcomes for patients undergoing pectus surgery. The evidence review was carried out in line with NHS England's standard methodology and only published, peer reviewed evidence is considered during this process.	Comments noted but no actions taken.
Individual Clinician	Support 2009 from NICE for intervention	No evidence was found in the literature to support	Comments noted but

Response (member of the Specialised Respiratory CRG; Hospital North Midlands)	Data is quite old and has only looked at cosmetic and psychological reasons in the main. On this basis suggestion is should not be provided. But flawed out of data information. This evidence is weak and contains little on the physiological impact of the deformity and changes post operatively. Results are not always obvious and the measure of spirometry is not relevant. Work looking at exercise capacity using formal exercise testing has shown significant reductions with the body becoming acid much earlier than normal individuals. Ie there is limitation of function. Careful of no evidence does not mean no benefit of the intervention. Would suggest procedure continues to be commissioned but in few eg 6-10 geographically appropriate centres, with surgery being performed after physiological and psychological assessments. ? move to highly specialised.	improvements in psychological outcomes for patients undergoing pectus surgery. The evidence review was carried out in line with NHS England's standard methodology and only published, peer reviewed evidence is considered during this process.	no actions taken.
Individual Clinician Response (member of the Specialised Cancer Surgery CRG)	Whilst I acknowledge that there are problems with the data in the literature and that the review team found little evidence that withstood intense scrutiny to support pectus surgery that does not mean that it has no value. (the relevant studies have not been done) Many of my patients having pectus surgery have their lives transformed by the surgery (as evidenced by immediate postoperative behaviour and outpatient follow up until bars removed). There is a dramatic improvement in posture and confidence and many of these patients return to a more normal existence having previously avoided any activities where they	Comments noted. The policy proposition has been developed in line with NHS England's standard methodology. Differences in outcomes depending on the severity of deformity were considered as part of policy development but no evidence was found to demonstrate that certain sub-groups have improvements in	Comments noted but no actions taken.

	might need to remove their top. I accept that patients with very mild pectus excavatum may not reap the same benefit but this is a group of patients I don't tend to operate on. I would suggest that NHS England sets a degree of severity which makes surgery justifiable using an index such as the Haller index for pectus excavatum. All patients operated on should be entered into a prospective registry. If this surgery is not supported then it will become a totally private procedure meaning that many patients with severe deformity will have to live with it because it is not funded by the NHS	clinical and psychological outcomes.	
Individual Clinician Response (Sheffield Teaching Hospital NHS Foundation Trust)	I disagree strongly with the concluding statement that "The evidence that was found is not sufficient to conclude that the physical psychological, social and behavioural benefits of surgical treatment of pectus deformities are sufficient to justify its use." I believe that there is insufficient evidence to state that surgery has sufficient benefits to justify its use. There is no doubt in my mind that, for some patients, there is a considerable negative psychological impact with pectus deformities. This is far more than the simple "vanity" seen in patients with other cosmetic variants. There is certainly a significant psychosocial element to pectus deformities. It seems, from my review of the evidence, that the assessment tools used in the studies quoted are not sensitive enough to pick up the degree of psychosocial impact. I agree that there is no convincing evidence of physical benefit to surgery (in terms of positive change in respiratory or cardiac function), but the psychological improvements can be profound and long lasting. I have had a good number of patients who have	Comments noted. The policy proposition has been developed in line with NHS England's standard methodology and only published, peer review evidence is considered in the development process	Comments noted but no actions taken.

	been very impressed with the results of surgery. The problem is that there has not been a concerted effort to gain high quality, appropriate, UK data in order to assess the benefits of surgery. The original UK Nuss procedure register purely served to record the performance of surgery, without any dedicated Patient Reported Outcome Measures (PROMs). The description of the Ravitch procedure in the document is closest to the modified Ravitch procedure, where the mobilised sternum is supported, using a variety of techniques e.g. using an Abrams bar placed behind the sternum, a posterior mesh support, or titanium plates and screws (Elastic Stable Chest Repair). The Abrams bar is removed within a few years of placement. Mesh or titanium plates and screws are permanent. As one of the first to employ in the UK, the Elastic Stable Chest Repair (Thoracic and Cardiovascular Surgeon · 2014 DOI: 10.1055/s-0034-1372333), I have seen a rapid return to full functionality in patients with severe deformity. I have got as far as writing a draft protocol for a multicentre, non-randomised, cohort study to explore the differences in clinical and PROMs outcomes according to the different techniques of repair. I have not considered the paediatric population, for which I do not offer surgery (this is done by paediatric surgeons in our region). There will certainly continue to be patients who seek surgical correction and I believe that, for some of these patients, surgical treatment within the NHS will offer an appropriate use of resources. The solution might well be for there to be a programme similar to the “Commissioning Through Evaluation” for stereotactic ablative radiotherapy (SABR) for pulmonary		

	metastases, wherein tariff reimbursement requires submission of an appropriate dataset. I have had advanced thoughts about an “appropriate dataset” and would happily work with appropriate authorities to deliver such a programme. An alternative would be for the NIHR to fund a clinical trial of pectus surgery in order to gain evidence. Again, I would be keen to facilitate that proposal.		