Engagement Report for Clinical Commissioning Policies

Unique Reference Number	1670
Policy Title	Total pancreatectomy with islet auto transplant for chronic pancreatitis (adults)
Lead Commissioner	Sarah Watson
Clinical Reference Group	Hepatobiliary and Pancreas
Which stakeholders were contacted to be involved in policy development?	Specialised Hepatobiliary and Pancreas CRG and registered stakeholders The proposal has been discussed at national meetings and all the units in the UK that could or may be interested in being involved have been involved. Diabetes UK ABCD (Association of British Clinical Diabetologists) AUGIS (Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland) The Pancreatic Society of Great Britain and Ireland The American Pancreatic Association IPITA (International Pancreatic Islet Transplant Association
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been involved	The RCP and RCS have been contacted and asked to offer advice through the Rare Diseases Advisory Group. Specific advice on the evidence was asked for from the National Clinical Director for Diabetes,
Which stakeholders have actually been involved?	The HPB CRG Views of a number of organisations have been taken into account following discussion; this proposal has been with NHS England for some time, allowing for significant input.
Explain reason if	Organisations declined the offer to participate in the

there is any difference from previous question	development of the policy
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.
How have stakeholders been involved? What engagement methods have been used?	Policy working group meeting and subsequent contact for policy development. Stakeholder engagement process. 14 day email engagement exercise with registered stakeholders
What has happened or changed as a result of their input?	Five responses were received from stakeholders. There was some comment related to the commissioning of the service, either service selection or clarification over funding of different aspects of the pathway. Broadly these will not be dealt with in the policy document but in the impact assessment and commissioning plan for the policy. The comment from the Office of an MP focussed on the clinical difficulties of managing chronic pancreatitis and set out the circumstances for constituent. Note was taken that the evidence supports the procedure ultimately being cost effective, particularly when considering wider socio-economic issues. The comments in relation to availability of dietetics were considered to focus not on the patient group specific to this policy but wider needs of patients with chronic pancreatitis. The PWG felt that the pathway for TPIAT candidates was well described with both consultant gastroenterology and diabetologist input and that no changes were therefore needed in the policy. It was agreed that there should be follow up discussions with the British Dietetic Association during Public Consultation.
How are stakeholders being	Stakeholders will be kept informed of the policy's progress through NHS England's consultation portal website.

kept informed of progress with policy development as a result of their input?	Stakeholders who sent in comments have had an email response.
What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement?	Four week public consultation – all stakeholders who responded answered ‘yes’ to question suggesting consultation of up to six weeks and comments were broadly supportive.

Appendix One - Stakeholder Feedback

Organisation Responding	Feedback Received	PWG response	Resulting Action
NHS commissioner	1 - Changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation. Lifelong oral therapies – need clarification on whether this needs to be provided by the surgical centre (and if so for life) and who is responsible for commissioning / payment for this element. The selection criteria/ process for a regional centre are not clear enough to allow commissioners to make choice / selection if more than one large volume provider in region. What activity / costs will stop for these patients and how will new funding be made available if not current commissioner of action that will stop? Coding for procedure should be included in policy	Noted All patients will already be on exocrine supplements prescribed by local GPs. This will need to continue post TPIAT. This needs to be dealt with via internal NHS England processes but the cost impact will be set out in the financial model for the service and in the impact assessment. The financial model that will set out the costs of the proposed service and impact on costs of current service Coding will be described in the Impact assessment	No changes made to the policy No changes made to the policy No changes made to the policy

Manchester University Foundation Trust	1 - changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation Our transplant and HPB teams have reviewed the documents and are supportive of proposals.	Noted	No changes have been made to the policy
NHS HBP consultants Oxford	Changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation As stakeholders we are in agreement with the changes made to this document and support its implementation. In Oxford based on our patient catchment and out of region referrals we see 15-20 patients from the Thames Valley, who we would consider for a TP-IAT per annum. In the absence of being able to offer a TP-IAT, these patients currently are managed inadequately with maximum support and opioid treatment. Approximately 2-4 patients per year receive a total pancreatectomy without an islet auto transplant (although we believe these patients would be better managed with TP-IAT if it were commissioned); we believe that the outcomes of these cases are sub-optimal. The remaining patients endure chronic pain and poor quality of life, and remain a clinical and financial burden on the NHS. Oxford is one of the centres in the UK that has the clinical expertise, infrastructure, Islet isolation facilities and experience in carrying out TP-IAT. To date we have carried out TP-IAT in a select few patients with funding for the islet isolation being borne by a research budget or privately. Therefore Oxford is well placed to offer the service of TP-IAT if it was approved. While the contents of the current version of the document under review are clear regarding the benefits the procedure offers, we would also want to seek clarity regarding the funding stream that would support the procedure if it is commissioned within the NHS.	Noted Noted Noted, if agreed the proposal would be subject to a procurement process This would be subject to NHS agreement	No changes have been made to the policy

Member of Parliament	1 - Changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation. My constituent, [redacted] first contacted my office in 2013 in desperation as she had visited several hospitals and specialists to determine the cause of her severe pain and vomiting. It was eventually discovered that she had Chronic Pancreatitis as a result of a congenital defect. Her condition became so severe that she was admitted to A&E over 50 times in a year. This has caused her and her family, especially her young daughter enormous distress and has severely disrupted my constituent's life who continues to suffer agonising pain. I would like to express strong agreement with the assertion in this document that patients and clinicians think that the TPIAT process could deliver significant pain relief and a reduction in the reliance on strong painkillers for those patients such as my constituent. My constituent has run out of options in pain management and for her, and others like her, the process would appear to be life changing. My constituent currently has a very poor quality of life. Her frequent admissions to A&E are very distressing for her, and her child and family, and have substantial cost and workload implications for local NHS Services. My constituent and her family are desperately hoping that she can return to a productive life if she can access the TPIAT treatment. It is extremely encouraging that the clinical evidence suggests that my constituent and others in her cohort, could experience enormous benefit from a procedure which will substantially relieve pain, vastly reduce the dependence on opiates, which will in turn deliver positive effects on her mental health, and is also unlikely to result in the development of brittle diabetes, unlike the Total Pancreatomy procedure.	Noted	No changes have been made to the policy proposition

	It would also appear from the evidence that the procedure could be cost neutral, but would have massive benefits in improving quality of life, and would also reduce the need for state support via benefits and associated health services. My constituent has had tremendous support from her parents, husband and child and friends in her local community. Accessing this procedure could be life changing for her and other CP patients who, even with support, endure a lonely fight against agonising pain.		
Sue Kellie The Association of UK Dieticians	The BDA requests that there are changes to the document to recognise the nutritional challenges that this group of patients face with considerable detriment to their long term health caused by micro and macro nutrient deficiencies. There are a small number of patients who will come to surgery, but many more will require consideration, and conservative management. This is an area that is grossly under recognised nationwide. Pancreatic specialist dietitians are uniquely qualified to manage the impact of both endocrine and exocrine failure on nutritional status, and to manage patients taking oral, enteral and parenteral nutrition in these setting. Patients require intensive nutritional support both in the pre-operative and conservative management section of this pathway - where appropriate management of exocrine and endocrine failure is required in patients. These patients are usually malnourished and have significant post prandial pain resulting in anorexia and food avoidance, with some requiring enteral feeding. In the post-operative setting these patients require long term follow up, and this too, is not currently supported in most centres.	The PWG have considered these comments and whilst they accept that the management of chronic pancreatitis could be improved nationally the cohort being discussed in the bid is a small percentage of this overall group who will be managed by an expert team and have been intensively managed for on average 4 years. The follow up for patients in the proposal includes ongoing management by the specialist team including Gastroenterologists and Diabetologists.	No changes made to the policy. It was discussed and suggested that there should be follow up discussions with the British Dietetic Association during Public Consultation.

	There is a high risk of osteoporosis and micronutrient deficiencies, and young female patients will need extensive support to ensure essential fatty acid absorption should they become pregnant. This is a benign disease, and whilst there is a reduced life expectancy, we need to ensure patient's long term needs are met. Specifically: 1) MDT assessment should clarify that this includes a review by a pancreatic or hepatobiliary advanced specialist dietitian with advanced and extended role in managing enzyme replacement and insulin requirements in complex situations 2) The pathway specifies long term follow up similar to that received by patients with coeliac disease - a minimum of annual specialist dietetic review with serum vitamin and mineral assessment and DEXA scanning etc.	The PWG did not agree with these comments.	