Engagement Report for Clinical Commissioning Policies

Unique Reference Number	1748
Policy Title	Addition of Rituximab to first-line standard chemotherapy for CD20 positive B-cell precursor Acute Lymphoblastic Leukaemia (adults)
Lead Commissioner	Rupi Dev
Clinical Reference Group	Chemotherapy
Which stakeholders were contacted to be involved in policy development?	A policy working group (PWG) was established in line with NHS England's standard methods. The draft policy proposition was sent to the following groups for comment: • Chemotherapy Clinical Reference Group (CRG); and • Registered stakeholders for the Chemotherapy CRG.
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been involved	All of the relevant Royal Colleges and professional societies have membership on the chemotherapy CRG. These include: • British Oncology Pharmacy Association; • Royal College of Pathologists; and • British Society for Haematology. Named representatives for each of these organisations were sent copies of the draft policy proposition and invited to provide comment.
Which stakeholders have actually been involved?	No responses were received from relevant Royal Colleges or professional societies. However, 7 responses were received from registered stakeholders.

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 input?	No changes have been made to the policy proposition as a result of feedback. There were 7 responses to stakeholder testing of which only one respondent actively supported the policy proposition. The remaining respondents raised the following issues:

	• In the view of stakeholders, the findings from one of the key studies had been misinterpreted by NHS England in drafting a not for routine commissioning policy. The emphasis on overall survival was felt to be incorrect and the primary outcome measure that needed review was the impact of adding rituximab to standard chemotherapy regimes on relapse rates. Respondents commented that in their opinion the evidence review did demonstrate a reduction in the relapse rate in CD20-positive B-ALL by a clinically meaningful and statistically significant level. • The cost effectiveness of treatment had not been taken into account as part of the decision-making process. Stakeholders felt improvements in relapse rates, as a result of the addition of rituximab, would result in a reduction in the use of second line treatments which were expensive to deliver. • Due to the rarity of adult acute lymphoblastic leukaemia (ALL) raised that large scale clinical trials were difficult to perform, highlighting that the key study in this evidence review took over 10 years to complete. Stakeholders did not feel that additional evidence would be generated for this indication. These comments have been reviewed by the PWG and are supported. It is important to note that the decision to proceed with a not for routine commissioning policy is based on clinical effectiveness and cost effectiveness is not considered till later in the policy development process. On review of the clinical evidence, Clinical Panel agreed that the "*degree of benefit demonstrated appears to be limited and below the threshold that Panel considered sufficient to take forward as a for routine commissioning recommendation*". For this reason, a not for routine commissioning policy has been developed.
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	There was mixed feedback on the period of consultation from stakeholders. Of the seven respondents, two respondents recommended a 6 week public consultation and three respondents recommended a 12 week public consultation; the

the NPOC Board to agree as a result of stakeholder involvement?	remaining two respondents did not provide any comment on the proposed length of public consultation. As a result of stakeholder feedback, the PWG is recommending an 8 week public consultation period.