Consultation Report

Topic details

Title of policy or policy statement:	**Selective internal radiation therapy (SIRT) for chemotherapy refractory / intolerant metastatic colorectal cancer**
Programme of Care:	**Cancer**
Clinical Reference Group:	**Radiotherapy**
URN:	**170102P**

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposition which recommends that Selective internal radiation therapy should be made available to adults with chemotherapy refractory / intolerant metastatic colorectal cancer where the metastatic disease is limited to the liver only.

2. Background

Selective internal radiation therapy (SIRT) offers an alternative treatment choice for people with metastatic colorectal cancer that has spread to the liver. It is used in cases where treatment choice is limited to best supportive and palliative care. It is important to note that the aim of SIRT is to control the growth of the cancer but it is not curative.

The treatment involves the injection of radioactive microspheres containing radioactive agents (either Yttrium-90 or Holmium-166) into the arteries in the liver. The microspheres lodge around the tumour(s) and release radiation over a number of days.

SIRT was previously available through a Commissioning through Evaluation (CtE) scheme. The policy proposition has been developed following consideration of the CtE findings, together with two new Evidence Reviews; the first looked at microspheres containing Yttrium-90 and the second looked at microspheres containing Holmium-166.

The policy proposition has been through stakeholder testing and public consultation.

3. Publication of consultation

The policy was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 17th August 2018 to 16th September 2018 Consultation comments have then been shared with the Policy Working Group (PWG) to enable full consideration of feedback and to support a decision on whether any changes to the policy might be recommended.

Respondents were asked the following consultation questions:

- Has all the relevant evidence been taken into account?
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?
- Are there any changes or additions you think need to made to this document, and why?

4. Results of consultation

There were eleven responses to the public consultation; three responses fully supported the policy and these responses were from a clinician, patient and member of the public. Responses were also received from the British Nuclear Medicine Society, British Society of Interventional Radiology, Interventional Oncology UK Committee, and from Industry including BTG PLC, Terumo Medical, Quirem Medical and the Association of British HealthTech Industries (ABHI).

Respondents raised concerns relating to: (i) inclusion criteria including no previous embolization and limiting the number of hepatic lesions to 5 or fewer; (ii) limiting the mode of treatment delivery to a single Yttrium-90 microsphere product, the exclusion of Holmium-166 microspheres; and (iii) the use of best supportive care as the only comparator within the evidence review.

Key themes are as follows:

- A respondent considered that excluding patients who have had previous embolisation was inappropriate. Level 2.
- Respondents felt that limiting the number of hepatic lesions to 5 or fewer was inappropriate. However, no new evidence has been submitted as part of the consultation process to support this change. Level 2.
- Respondents felt that both yttrium products (resin and glass) should be considered as equivalent and referenced in the policy. Level 1.
- The manufacturer of holmium-166 felt that this product should be considered as equivalent and included in the policy. Level 2.

- Some respondents considered that other comparator treatments should have been used during the evidence review. However, the PWG has confirmed that there is no standard 3rd line treatment for chemo-refractory patients which could have been used as a comparator other than best supportive care. Level 2.

5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity
- Level 2: Issue has already been considered by the Clinical Reference Group (CRG) in its development and therefore draft document requires no further change
- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document
- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility

6. Has anything been changed in the policy as a result of the consultation?

The PWG has considered the responses received and has responded as follows:

- To develop this policy, in addition to the evidence reviews, the results of the NHS England SIRT CtE programme were included. It is understood that the evidence reviews highlight the lack of well-designed prospective comparative studies of SIRT and best supportive care to provide reliable evidence of survival outcomes. However, the subgroup analyses of the register data within the CtE evaluation showed that the absence of extrahepatic disease (also termed liver dominant disease), fewer liver tumours, smaller tumour to liver volume percentage, were factors associated with a survival benefit. This subgroup analysis forms the basis of the policy proposition. The PWG accepts that the National Institute of Health and Care Excellence (NICE) considers it unlikely that any further sub group analysis to assess benefit in patients with 10 hepatic tumours or fewer would be valid or may be inconclusive because of insufficient data.
- The requirement for patients to have had no previous embolisation was one of the eligibility criteria for patient selection to participate in the SIRT CtE programme. This was considered at the time to be an important patient safety issue. The policy proposition has been developed in line with the findings from the CtE programme and reflects the clinical criteria used in this programme. Although the PWG acknowledge that it is likely that SIRT is safe after previous embolization and support a change to

the eligibility criteria, no new data or evidence has been submitted by stakeholders to support this. Therefore no changes have been made to the policy proposition as a result of this feedback.

- The CtE data has formed the basis of this policy and glass and resin products were both included within the CtE from inception. No analysis, as part of the CtE programme, was planned based on the two different technologies. The final analysis for the evaluation report was undertaken on all patients and it did not distinguish between glass or resin. As a result, the PWG is recommending that in consultation with Clinical Panel, the policy proposition be amended to include the use of glass microspheres.
- When the CtE programme was first set up Holmium-166 was not available commercially in UK. No centre in UK has experience of using it. The original NICE Interventional Procedures Guidance 410 was specific to Yttrium-90. In addition, the PWG agrees that the CtE scheme did not include Holmium-166 based treatments and that the CtE results are therefore not generalizable to other forms of SIRT. Therefore the PWG considers no change to the policy is required.
- The PWG considers that the only comparator is best supportive care as there is no standard 3rd line treatment for these patients.

Therefore, only one change has been made to the content of this policy which is to include both resin and glass Yttrium-90 products in the policy proposition.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposal?

None.