# Consultation Report

## Topic details

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| **Title of policy or policy statement:** | **Selective internal radiation therapy (SIRT) for the treatment of chemotherapy refractory or intolerant, unresectable primary intrahepatic cholangiocarcinoma** |
| **Programme of Care:** | **Cancer** |
| **Clinical Reference Group:** | **Radiotherapy** |
| **URN:** | **1771** |

## 1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposition which recommends that SIRT should be made available for the treatment of chemotherapy refractory or intolerant, unresectable primary intrahepatic cholangiocarcinoma.

## 2. Background

Intrahepatic cholangiocarcinoma is a rare type of primary liver cancer that develops in the bile ducts. Surgery is the primary treatment option, however, the majority of cases are diagnosed where the cancer is too advanced for surgery to be effective. Where this is the case, palliative treatment is offered to manage symptoms and prolong life, including chemotherapy, some surgical procedures (such as bile duct bypass, stent insertion), and best supportive care.

Selective internal radiation therapy (SIRT) is a way of giving radiotherapy treatment and involves the injection of radioactive spheres into the arteries in the liver. The spheres lodge around the tumour(s) and release radiation over a number of days. The aim of SIRT is to control the growth of the cancer but it is not curative.

SIRT was previously available via a Commissioning through Evaluation (CtE) scheme for this clinical indication and the policy proposition has been developed following consideration of the CtE findings, together with a fresh Evidence Review. Neither published research nor the CtE findings provided convincing evidence about the benefits of SIRT compared to best supportive care.

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 14th September 2018 till 14th October

2018. Consultation comments have then been shared with the Policy Working Group 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 fifteen responses to the public consultation; twelve responses fully supported the policy and these responses were from the Royal College of Radiologists, clinicians, patients and members of the public.

The remaining three responses, received from BTG PLC, Terumo / Quirem Medical and an individual patient, raised concerns relating to: (i) lack of evidence of patient impact other than financial; (ii) omission of new data; (iii) the use of NICE evidence; and (iv) lack of reference to holmium -166 microspheres.

Key themes are as follows:

- One respondent considered that no attempt had been made to describe the patient impact other than to suggest that there has been insufficient evidence produced by the three studies. This respondent referenced additional papers for consideration. Level 2.
- One respondent considered that it would be the useful for clinicians, NHS Trusts, commissioners and patients to have a similar output from the NHS England policy proposal as the NICE Interventional Procedure Guidance recommendation (consultation published in May 2018; final guidance expected on 31 October). Level 2.
- One respondent requested the inclusion of the holmium-166 technology description in the policy to ensure a consistent description of the SIRT procedure in this as the metastatic colorectal cancer policy. 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 PWG 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.

All responses received during public consultation have been assessed as Level 2.

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

The Policy Working Group and Programme of Care have considered the responses received and have responded as follows:

- In developing this policy, the findings of two evidence reviews and the results of the NHS England SIRT CtE programme were considered. The additional studies referenced have been reviewed; these studies did not meet the PICO criteria and therefore would have been excluded from the evidence reviews. An evidence report has been completed and no change to the policy proposition is recommended.
- The NICE draft IPG (May 18) states that "*Current evidence on the safety of selective internal radiation therapy (SIRT) for unresectable primary intrahepatic cholangiocarcinoma shows that there are well-recognised, serious but rare safety concerns. Evidence on its efficacy is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research***."** As a result, no change to the policy proposition is recommended.
- There is no published research for the use of Holmium microspheres in the treatment of intrahepatic cholangiocarcinoma. In addition, when the CtE programme was first set up Holmium was not available commercially in UK and no centre in UK has experience of using it. As a result, no change to the policy proposition is recommended.

No changes have been made to the policy proposition as a result of public consultation.

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

None.