Engagement Report for Specialist Cancer Services (adults), Hepato-Pancreatic Biliary (HPB) – Primary Liver, Secondary Liver, Perihilar Biliary Tract and Gallbladder Cancers Service Specification

27 July 2022, Version 2

Topic details

Programme of Care	**Cancer Programme of Care**
Clinical Reference Group	**Cancer Clinical Advisory Group**
Unique Reference Number (URN)	2260

1. Summary

This report summarises the feedback NHS England received from engagement during the development of the Specialist Cancer Services (adults), Specialist Hepato-Pancreatic Biliary (HPB) – Primary Liver, Secondary Liver, Perihilar Biliary Tract and Gallbladder Cancers Service Specification, and how this feedback has been considered. Seven responses were received from stakeholder groups including clinicians, medical devices manufacturers, NHS Trusts, patient charities and individual patients with knowledge and experience of treatment and care for HPB primary liver, secondary liver, perihilar biliary tract and gallbladder cancers.

Feedback was positive overall, with stakeholders registering their broad support for the service specification requirements, standards, and outcomes proposed.

Background

In 2016-18 there were an average of 5,240 new cases of liver cancer diagnosed in England, which is an incidence rate of 10.12 per 100,000 (CRUK). There are five main types of cancer affecting the liver, the two most common are hepatocellular carcinoma (HCC) and bile duct cancer. Liver cancer is the 18th most common cancer and is the second fastest rising cause of cancer death over the past decade in the UK (British Liver Trust). Liver cancer has one of the lowest survival rates of any cancer, with only 13% of people surviving for 5 years or more (British Liver Trust).

The new HPB primary liver, secondary liver, perihilar biliary tract and gallbladder cancers service specification has been formed from the current HPB Service Specification (2013), which covers both benign and malignant disease. There will also be a new service specification covering HPB pancreatic and periampullary cancers. On approval and publication, the current HPB service specification will be amended to focus solely on benign disease.

The service specification has been developed to set out the must-do requirements for providers and:

- Reflect current care pathways;
- Reference up to date national guidance and guidelines, as well as appropriate national policy, for example Faster Diagnosis and elective recovery;
- Incorporate meaningful quality outcome measures which will support improved outcomes and experiences of care; and
- Avoid duplication with other schedules within the NHS Standard Contract.

It is expected that the new HPB primary liver, secondary liver, perihilar biliary tract and gallbladder cancers specification will support Integrated Care Boards (ICBs) to take responsibility for the commissioning of HPB specialist cancer services when delegated.

The new service specification is not expected to change the provider landscape or overall service delivery. As a result, the revised service specification is expected to be cost neutral to NHS England and other parts of the NHS.

In accordance with usual NHSE processes, this service specification was developed with the support and input of a Specification Working Group (SWG), comprising representation from HPB cancer clinical experts and patient and public voice representatives, including the British Liver Trust.

2. Engagement Results

3.1 Stakeholder Testing

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to ‘make arrangements’ to involve the public in commissioning. Full guidance is available in the

Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The service specification was sent for stakeholder testing for 2 weeks from 3rd July to 17th July 2023. Effort was made to review and update the stakeholder engagement list to ensure that relevant professional societies and patient groups were contacted and asked to comment. The feedback received has been reviewed by the Specification Working Group Chair and the Cancer Programme of Care (PoC) to enable consideration of feedback and to support a decision on whether any changes to the specification might be recommended.

Respondents were asked the following questions:

- The minimum population size in the service specification is based on recommendations made within the National Peer Review Programme HPB Cancer Measures (2013) which recommend annual team case throughput of 150 liver surgical procedures (75 of which should be major - 3 or more segments) for neoplastic disease or suspected neoplastic disease. The Specification Working Group are considering amending the annual team case throughput recommendations to in excess of 100 liver resections for primary and metastatic liver tumours to reflect evidence-based changes to clinical practice and treatment pathways. To what extent would you be in support of this change?
- If the case throughput requirement was set to in excess of 100, what impact, if any, do you think this would have on standards of care?
- If the case throughput was set to in excess of 100, what impact, if any, do you think this would have on providers and multi-disciplinary teams?
- Are the service quality outcomes appropriate to the service? If no, what quality outcome measures would you want to see included in the service specification?
- In updating the service specification, we have clarified that HPB Primary Liver, Secondary Liver, Perihilar Biliary Tract and Gallbladder Cancers Services must be co-located with interventional radiology services and that there must be 24 hours a day/7days a week access – we have made this change based on clinical advice which also suggests that this wording reflects current provider arrangements and is not a substantive change. To what extent do you support this change?
- If the requirement to have 24 hours a day/7days a week access to interventional radiology services was included in the service specification, what impact, if any, do you think this would have on providers and multi-disciplinary teams?
- The service specification proposes that providers of HPB Primary Liver, Secondary Liver, Perihilar Biliary Tract and Gallbladder Cancers Services must be a member of a Cancer Alliance as this reflects the current arrangements for the

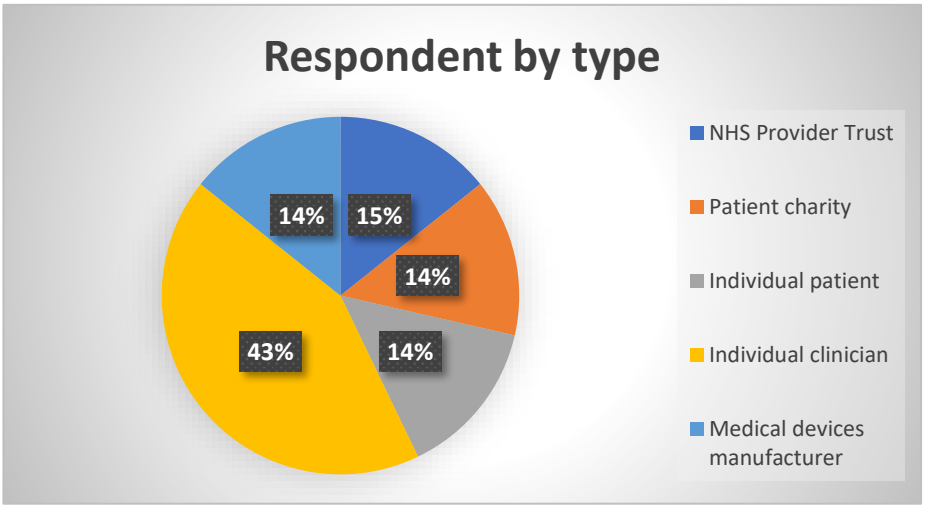
local coordination of cancer care. Do you support the inclusion of this requirement in the service specification? If no, can you explain why?

- Do you have any comments on the proposal? If yes, please describe below, in no more than 500 words, any comments on the proposal as part of this initial 'sense check'.
- Do you support the Equality and Health Inequalities Impact Assessment?

3.2 Stakeholder testing results and summary of participants

5 responses were received:

- 1 NHS Provider Trust
- 1 Patient charity
- 1 Individual patient
- 1 Medical devices manufacturer
- 3 Individual clinicians



Overall, the feedback received was positive, with stakeholders registering their broad support for the service specification requirements, standards, and outcomes proposed.

In terms of specific questions asked; all seven respondents strongly supported the clarification in the specification that HPB Primary Liver, Secondary Liver, Perihilar Biliary Tract and Gallbladder Cancers Services must be co-located with interventional radiology services and that there must be 24 hours a day/7days a week access. All seven respondents also supported the inclusion of the requirement in the specification for providers of HPB Primary Liver, Secondary Liver, Perihilar Biliary Tract and Gallbladder Cancers Services to be a member of a Cancer Alliance. All seven respondents confirmed their support for the Equality and Health Inequalities Impact assessment.

On the question of amending the team case throughput requirements to in excess of 100 liver resections for primary and metastatic liver tumours to reflect evidence-based

changes to clinical practice and treatment pathways, four respondents strongly supported the change, one respondent somewhat supported the change, one respondent neither opposed nor supported the change, and one respondent strongly opposed the change. Some feedback on this question surrounded this amendment having no impact on standards of care or Providers and multi-disciplinary teams owing to it being evidence-based and in line with current clinical practice. Other feedback from the respondent who strongly opposed the change surrounded concerns that this would create too much work which may also impact on safety. This specific question was included to gauge support for a possible amendment in anticipation of updated guidance being published by the Association of Upper Gastrointestinal Surgeons (AUGIS). It has since been confirmed that the guidance will not be published in time for inclusion in the service specification, however, owing to the support noted for amending the case throughput, NHSE will look to pursue this if/when the updated guidance is published.

Additional feedback surrounded a request to consider an addition of anaesthetics for endoscopic procedures as an essential facility and whether two endoscopy practitioners as core members of the specialist multi-disciplinary team was adequate, and a request to consider including minimum numbers of interventional radiology treatments per year alongside the surgical requirements. There were also some minor points of clarity regarding the type of biopsy outlined in the overall patient pathway.

The review of stakeholder responses to engagement, and subsequent decisions on whether any changes to the specification might be recommended are outlined in Section 4 below.

A 13Q assessment has been completed following stakeholder testing. The Programme of Care has concluded that the service specification and proposed amendments does not constitute material changes to the way in which services are delivered or the range of services available and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group on 17th August 2023.

4 How has feedback been considered

Responses to engagement have been reviewed by the Specification Working Group and the Cancer PoC 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 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.

The following themes were raised during engagement:

Respondent category	Key themes in feedback	NHS England Response
	Relevant Evidence	
Patient charity	More experienced interventional radiologists and radiology department staff would be required to cover the service if there was a requirement for it to be collocated and 24/7 availability.	Level 4. Out of scope of the specification. For local management by Trusts. **No change.**
Medical devices manufacturer	Page 10 lists the essential staff for the specialist MDT. Two endoscopy practitioners, between them, covering endoscopic ultrasound and ERCP – if only one of these individuals can perform endoscopic ultrasound techniques, this will leave gaps in the service during study leave, sickness, annual leave, or other absences.	Level 2. Section 7.4 identifies the minimum staff requirements for the Service to deliver a compliant sMDT. This section is not a reflection of the total number of staff within a Service. The service specification states: *"The number of people required to fulfil each role will depend on the team's workload."* **No change.**
Individual clinician	Consider making minimum numbers of IR treatments required per year alongside the surgical requirements. E.g. X ablations/year, Y TACEs/year and Z SIRTs/year. Happy to help draft those numbers.	Level 2. The recommendations made in relation to minimum volumes have been fully considered by the SWG, including the potential to include IR procedures within the minimum volumes outlined. The final proposals reflect the current evidence base which surrounds surgical intervention. There is currently no new published guidance

		relating to minimum numbers of IR treatments required for this tumour type. The SWG concluded that it was important to retain surgical expertise and that minimum volumes for surgery will, by design, also generate adequate levels of IR activity. **No change.**
Individual clinician	There may be a pressure to offer more surgery to keep units as recognised centres.	Level 2. The recommendations made in relation to minimum volumes have been fully considered by the SWG and proposals to amend numbers by centre reflect current practice and evidence base. **No change.**
	Impact Assessment	
Individual patient	Changing the case throughput requirement will lead to too much work for the MDT and make it less safe as a result.	Level 2. The recommendations made in relation to minimum volumes have been fully considered by the SWG and proposals to amend numbers by centre reflect current practice and evidence base. **No change.**
	Current Patient Pathway	
Patient charity	There is lots of mention of holistic needs assessment in the document. It is really important that when an issue is identified in the assessment, such as the need for psychological input, that the appropriate resources are available in a timely and accessible fashion – counselling services, specialist social worker, benefits advisor etc. Our experience is that liver cancer patients often report poor access to basic care - many report never having seen a specialist cancer nurse for example.	Level 2. The proposed specification states the Provider must be a member of a Cancer Alliance and ensure that the Service: *"Has appropriate multi-modal prehabilitation and rehabilitation arrangements and enhanced recovery protocols in place, with services that provide Specialist Dietitians, Physiotherapy, Occupational Therapy and Psychology."* **No change.**
Individual clinician	I think that there should be specific comments on the IR procedures offered.	Level 2. Considered by SWG during specification development. Agreement to include wording "vascular and non-vascular interventional radiology" to avoid being too

		prescriptive and avoid the spec becoming out of date quickly. **No change.**
Individual clinician	Patients should not be discussed in centres/networks where the whole array of IR procedures are not on offer. E.g. discussing a patient with HCC, where SIRT is not performed, and this may be the post appropriate modality but is not offered to the patient as that MDT/network does not perform SIRT.	Level 2. Section 7.1 describes the service model which states that Providers must have appropriate pathways and network arrangements to support specialist treatment and procedures for primary liver, secondary liver, perihilar biliary tract and gallbladder cancers, which includes IR. Providers must have a fully constituted sMDT in place to ensure all appropriate treatment options are considered for individual patients. Section 7.4 identifies the essential staff groups for a compliant sMDT which includes: • 2 radiologists at least one of which should be an interventional radiologist so that interventional and diagnostic radiology are covered. **No change.**
	Potential impact on equality and health inequalities	
Patient charity	Should we also be mentioning access to interpreters and written info in languages other than just English in recognition of equality, diversity, and personalised information?	Level 2. This is covered in section 13.2 of the standard contract which states: *"The Provider must provide appropriate assistance and make reasonable adjustments for Service Users, Carers and Legal Guardians who do not speak, read, or write English or who have communication difficulties (including hearing, oral or learning impairments). The Provider must carry out an annual audit of its compliance*

		with this obligation and must demonstrate at Review Meetings the extent to which Service improvements have been made as a result." **No change.**
	Changes/addition to service specification	
Individual clinician	A pharmacist should form part of the essential staff group as they are key for delivering SACT safely.	Level 4. This is covered within the SACT specification: *"A consultant practitioner (such as an appropriately trained and identified registered pharmacist or nurse at consultant level) may provide the link between the chemotherapy service and the multi-disciplinary team."* **No change.**
Medical devices manufacturer	The current document has several pages where links are missing e.g., links to commissioned services. This makes it difficult to consult on the document as it is currently incomplete. Will there be an opportunity to revise the complete final draft prior to finalisation and publication?	Level 2. Links to commissioned services list will be included when available prior to publication. **No additional action necessary.**
Medical devices manufacturer	Page 6, overall patient pathway, within the "Diagnostics" boxes is listed percutaneous EUS, is this referring to ultrasound guided endoscopic drainage or is it referring to percutaneous drainage?	Level 1. Service specification amended to clarify IR percutaneous biopsy and EUS guided biopsy. **Amended.**
Medical devices manufacturer	Page 7, within the box labelled "Diagnostics" suggest consideration of the addition of "+ Biopsy" be considered for addition to this sentence	Level 1. Service specification amended to add biopsy to the sentence as suggested. **Amended.**
Medical devices manufacturer	Anaesthetists form an importantly increasing role in some ERCP procedures and consideration should be given to whether this is an essential staff group.	Level 1. Service specification amended to add endoscopic in the second bullet point of section 7.5 which outlines essential equipment and/or facilities. **Amended.**
Individual clinician	I think this will not likely be a problem as the specialist liver centres will have 24/7 IR on call. This does of course need to be confirmed and appropriately budgeted.	Level 1. Service specification amended to clarify 24/7 access relates to emergency procedures. **Amended.**

	Routine diagnostic work/biopsy cannot be supported out of hours, but access to IR to manage complications in these patients is needed.	
	Generic feedback/questions	
Medical devices manufacturer	Page 6 outlines the overall patient pathway, noting this is specialised commissioning. The consumables for per oral cholangioscopy are currently rechargeable to the commissioner – usually local commissioner. Will these consumables be rechargeable to Specialised Commissioning when used in a level 3 service?	Level 2. The patient pathway is clearly illustrated in the service specification. **No change.**
Patient charity	Cancer alliances have often not covered liver cancer in the same way as other cancers. They should have a role in ensuring that liver cancer is more effectively planned across local areas and monitoring elements to ensure (for example) effective surveillance, faster diagnosis etc. Cancer alliances should have specific liver cancer priorities to focus on.	Level 4. Out of scope of the specification. For local management and implementation by Cancer Alliances.
Medical devices manufacturer	The document lists relevant NICE guidance (page 12). How will the latest clinical developments and NICE guidance be communicated to specialist centres?	Level 4. Out of scope of the purpose of the service specification documentation. **No action required.**
Medical devices manufacturer	Will there be consequences for specialist units not adhering to NICE guidance? How will adherence be monitored and reviewed?	Level 4. Out of scope of the purpose of the service specification documentation. Contracts with Providers monitored and managed by Commissioners locally. **No action required.**
Medical devices manufacturer	We would value an opportunity to comment on the service specification for benign HPB disorders and the service specification for other cancers e.g., periampullary cancers when this becomes available.	Level 4. Request shared with Internal Medicine PoC who are leading the development of the non-malignant HPB specs.

5 Has anything changed in the service specification as a result of the stakeholder testing and consultation?

The feedback received was reviewed by the Specification Working Group Chair and the Cancer Programme of Care (PoC) to enable consideration of feedback and to support a decision on whether any changes to the specification might be recommended.

The following changes based on the engagement responses have been made to the service specification:

- Four level 1 amendments have been made to the service specification as listed in the table above.

6 Are there any remaining concerns outstanding following the consultation that have not been resolved in the final service specification?

Three changes have been made to the service specification to improve clarity and/or clarity (level 1).

The 13Q assessment has been completed following stakeholder testing. The proposal and the 13Q will be reviewed at the PPVAG meeting on 17th August 2023.

Confirmation has been received that public consultation is not required.

7 What are the next steps including how interested stakeholders will be kept informed of progress?

A summary of the feedback from stakeholder engagement will be made available to the registered and relevant stakeholders.