Engagement Report for Specialised Hepatobiliary and Pancreas (HPB) Services (Adults) Service Specification

February 2025, Version 1

Topic details

Programme of Care	Internal Medicine Programme of Care
Clinical Reference Group	Hepatobiliary & Pancreas
Unique Reference Number (URN)	A02/S/a - 250501

1. Summary

This report summarises the feedback NHS England received from engagement during the amendment of the specialised Hepatobiliary and Pancreas specification, and how this feedback has been considered. Nine responses were received from healthcare organisations, device manufacturers, clinicians, regional commissioner and individuals with knowledge and experience of treatment and care for HPB conditions.

Feedback was positive overall, with stakeholders registering their broad support for the suggested amendments to improve access. The Specification Working Group (SWG) feedback emphasised the importance of 24/7 access to specialist hepatology centres, highlighting that adequate staffing and interventional radiology resources are essential to meet this requirement effectively. Stakeholders also noted the necessity of a multidisciplinary team (MDT) approach for managing complex cases while cautioning against its use as a financial control mechanism. They expressed a desire for enhanced metrics to support early intervention and a smooth integration of primary and secondary care services along the patient pathway. The SWG will communicate this to the Hepatobiliary and Pancreas Clinical Reference Group (CRG), who are already working with key stakeholders within NHS England to consider whether these insights can be integrated into the final service specification, if they address gaps in existing service delivery and promoting equitable access to care across regions.

2. Background

The proposal is an update of the currently published Hepatobiliary and Pancreas (HPB) service specification. This will replace the previous HPB service specification (2013). The original specification included both cancer and non-cancer elements. This revision focusses on the non-cancer elements of specialised hepatobiliary and pancreas care, as the cancer-related liver and pancreas care has been explained in a separate specification prepared through the Cancer Programme of Care. This change enables a greater focus on the non-cancer elements of specialised HPB care.

This revised service specification has been developed with the aim of improving outcomes for patients with liver, biliary and pancreatic conditions by:

- fostering collaboration among healthcare providers to deliver networked integrated and patient-centred care, aimed at ensuring
- timely access to high-quality medical and surgical treatments, whilst
- promoting prevention, and early intervention where needed, including pathways to transplant where this will be beneficial.

The commissioning plan supporting implementation of this specification does not anticipate either an increase or reduction in the number of commissioned specialised hepatobiliary centres as a direct result of this specification revision. More formalised collaborative regional liver referral networks have been described, aiming at ensuring better and timely linkage across the whole patient pathway, improving referral and escalation to specialised liver and pancreatic care, where needed.

The specification describes both the medical and surgical service for adults with conditions such as acute or chronic liver failure, complications of chronic liver disease requiring surgical or radiological intervention, chronic hepatitis viral infection, chronic or hereditary pancreatic disease, and complex hepatobiliary surgery, among others.

The specification is supported by a series of existing and revised quality metrics for both the liver and pancreatic elements of the specification, split into two separate quality dashboards.

Service specifications form part of a schedule within the NHS Standard Contract, and they describe the service requirements and standards to be met. This specification relates specifically to the elements of the patient pathway where NHS England is the legal commissioner.

It is expected that the Service Specification will support Integrated Care Boards (ICBs) to take responsibility for the commissioning of these services when delegated.

3. 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 during September 2024 for 3 weeks. Efforts were made to review and update the stakeholder engagement list to ensure that relevant professional societies, including radiology, commissioners and patient groups were engaged and asked to comment. The comments received were shared with the Specification Working Group to enable full consideration of feedback and to support a decision on whether any additional changes to the specification might be recommended.

Respondents were asked the following questions:

1. Do you support the proposed publication of a new service specification, following the publication of the new liver cancer and pancreatic cancer service specifications?

2. The 24 hours a day/7 days a week access to a specialist hepatology centre has been included in the service specification. What impact, if any, do you think this would have on providers and multi-disciplinary teams?

3. Is a mandated multi-disciplinary team approach appropriate for the service and the conditions to be treated?

4. Is the service description clear and concise?

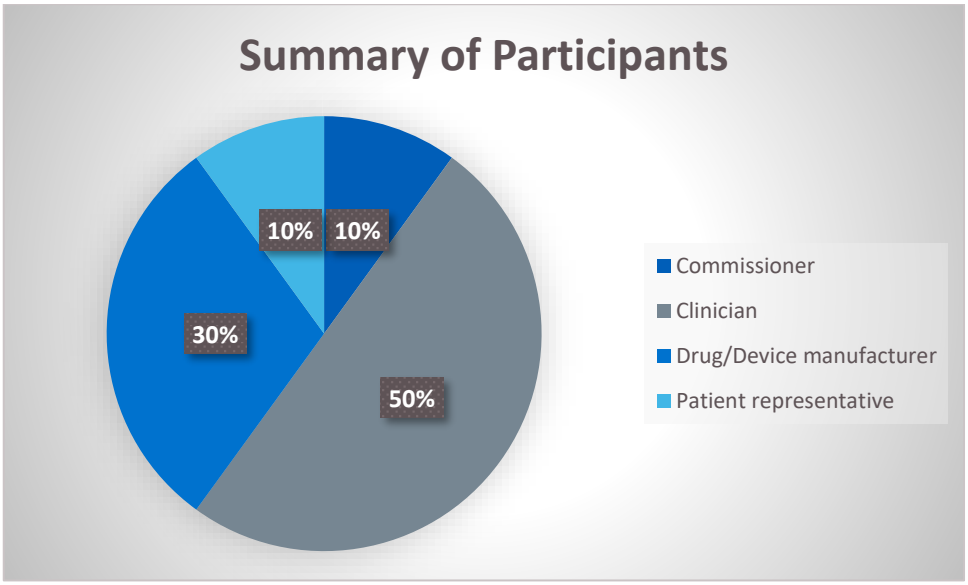
5. Do you believe that there is any additional information that we should have considered as part of this process?

6. Do you agree the quality outcome metrics selected are appropriate for the pancreas service?

7. Do you agree the quality outcome metrics selected are appropriate for the liver service?

8. Do you support the Equality and Health Inequalities Impact Assessment (EHIA)?

3.2 Stakeholder testing results and summary of participants



Ten responses were received:

- One response from a clinical professional society
- Four further responses from clinicians
- One response from a patient representative
- One response from a commissioning representative
- Three responses from industry.

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

Responses have been carefully considered by the Specification Working Group 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.

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

The comments received were considered and reviewed by the Specification Working Group as part of the process to support decisions about any changes that should be made to the service specification and EHIA.

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

- Seven Level 1 amendments have been made to the service specification or the equality health impact assessment.
- in addition, two amendments have been made to the EHIA to incorporate feedback relating to the potential impact on people who face inequalities within health.
- A number of considerations have been logged which will be addressed in the commissioning plan that will support the service specification implementation once approved.

There are no outstanding issues.

6 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.

Further discussion will take place with the NHS England Patient and Public Voice Assurance Group but is it not recommended further public consultation is required.

The stakeholder engagement report will be considered by CPAG alongside the revised specification.

The following responses were raised in the feedback received and have been anonymised:

Response	Criteria	Action
Structure of the service		
Supportive of the specification, and agree need for access to 24/7 interventional radiology	2	The specification mentions the need for 24/7 access to key services, and the commissioning plan will set out that where this is not already the standard, this will need development.
Providing a 24 hour service will require additional resourcing of staff in order to maintain high quality care. Resourcing must not come from the already established team as has often been the case when making other areas of the NHS have a 24/7 service. The resourcing must increase by 2/7 in order to achieve this. 24/7 access to specialist hepatology centre is a vital addition, this will require the formation of regional networks to deliver, but will lead to significant improvements in patient care.	2	The access to on-call consultant cover was already a requirement of the previous specification, and this is no change, although appreciate that it may not have been in place at all centres. The commissioning plan will set out how this needs to develop.
Will require sufficient workforce to deliver these rotas. Surgical HPB rotas already exist and are embedded within the existing re-sectional centres.	2	Noted, and to be highlighted in the commissioning plan
Can the Specialised Hepatology centres have Pharmacists called out alongside the Specialist Nurses and Dieticians.	1	Specification has been amended to highlight the importance of the wider MDT expertise

Relationship across the patient pathway		
The specification sets out the inter relationship between non specialised and specialised HPB services well and this should be noted as part of an opportunity for delegation.	2	As the consultation points out the Service specifications form part of a schedule within the NHS Standard Contract, which means that they can only mandate elements of the pathway where NHS England is the legal commissioner. However, the inter-relationship with the wider patient pathway will be drawn out in the commissioning plan
There is a need to agree and plan the primary care part of this and how it integrates with secondary care services.	4	Out of scope for the current specialised specification, however noted for the commissioning plan, which will include local and regional networks.
The development of more networked care is welcomed and supported alongside the need to look at the whole pathway of care and early and accurate diagnosis and intervention recognising that by the time many patients present in hospital opportunities may have been missed. The development of clinical networks (similar to other CRGs) will revolutionise care for hepatology patients and is an important forward step.	2	Noted for Commissioning plan, including for local and regional networks
An MDT approach is appropriate for the initiation of specialist care and initial management of specialist conditions and when the patients are complex and unstable. MDTs should not be used as a financial control mechanism. Mandating an MDT could lead to prescribing and treatment decisions that might not be in the best interest of the patient simply because the treating clinician does not have the time to take the patients case to the MDT board.	2	The SWG feels that a balance is needed to minimise harm whilst enabling access to appropriate treatment. Standardised protocols may strike the balance. NICE guidance supports this approach, and is the basis for inclusion in the specification. Services should consider an MDT approach as an opportunity, rather than a mandate

Link with Cancer services		
This specification appears to commission services for benign HPB/hepatology conditions which are already provided in a de-facto manner by the established HPB regional resection centres. Although it's important to maintain standards for delivery of such benign services, I am unsure as to the need to commission new services when these already exist. The service description seems exclude the fact that these services are already delivered by commissioned HPB resection or HPB/transplant centres. Thus the specialist hepatology centres should be collocated with the regional HPB surgical centres which in turn should be those established resection/transplant centres. I'm not sure the specification as currently written makes this necessity for collocation to medical and surgical re-sectional services clear.	2	The SWG is supportive of co-location. This is optimal for services to develop in a harmonised way, but intention is to not destabilise the current commissioning landscape. Formalised links including escalation routes to call om wider expertise have been included in the service specification.
These specifications excludes patients with cancer and the crucial issue of timely referral of all patients to the re-sectional HPB MDT.	4	The SWG agrees, however, cancer services, while co-existing alongside this service, sit outside this specification, and have their own pathway and structures.
Missed opportunity to integrate hepatology with benign HPB with existing resectional HPB cancer services.	4	Out of scope of this specification

Clinical Procedures		
BSG Cholangiocarcinoma and HCC guidelines. [*should be included*].	1	These have been identified, and a link added to the service specification.
Specialist Liver Critical Care Interventions (PLEX for acute liver failure).	1	Specification has been amended to include this intervention. Hepatology centres should also provide HPB endoscopy as part of a specialised endoscopy network.
The HPB Surgical Centres are required to provide specialist endoscopy including ERCP and EUS. However, it would also be appropriate for the specialist Hepatology units to provide these services (as they already do in most cases).	1	SWG agrees and the specification has been amended with this inclusion. Specialised hepatology centres should include this expertise.
We would like the Other national standards section to also include the TA896.	1	SWG agrees, and this has been included in the list of supporting documents.
We acknowledge 6.1 Service Aims point 4 “To ensure that all patients with complications of portal hypertension are assessed appropriately at an early stage and that those who might benefit from a TIPSS procedure have timely access to the specialist centre and the expertise they offer”. It is hoped the proposed service model in (7.1) will support appropriate patient access to TIPSS and reduce regional health inequalities by utilising the new network approach to the patient pathway for “people at risk of clinically significant portal hypertension including varices” who will benefit from TIPSS.	2	SWG agrees that the specification and supporting quality metrics will monitor patient access to transjugular intrahepatic portosystemic stent shunt procedures, with the aim of identifying and addressing inequities in access to this procedure.
In section 6.1 (point 9) to also include the initiation and optimisation of Hepatitis D super infection and the assurance that for every patient with Hepatitis B has been tested for Hepatitis D.	1	SWG agrees and the specification has been amended with this inclusion.

We would like to see included in the Specialised Hepatology Centres responsibility a paragraph that truly supports the treatment of patients nearer to their homes and reduces the travel burden that many patients have.	2	This is already intended within the specification, and also built into the HCV networking specification.
Could the Specialised Service Specification be requested to mandate the development of shared care protocols for specialised medicines that once approved by the MDT, initiated and the patient stabilised, can be monitored and supplied closer to where the patient lives. Currently there is wide variation across HCV/HBV/HDV and PBC in the way patients are referred and care continued across England.	3	The specification can be broadened to seek services working towards protocols for shared care with Patient Group Directions (PGDs) and expanded prescriber permissions, but we need to acknowledge the current medicines access rules and limitations.
The Metrics are very specialist focussed and hospital metrics, I would like to see, as time moves on, increased metrics to support earlier identification and management prior to specialised centres. Also targeted screening for known patient cohorts, identification can lend itself well to ICB services.	2	Noted for consideration for future metrics development for the whole patient pathway, including for local networks.

I would like to request that the reference section of this Service Specification is updated with 2 key pieces of NICE guidance released in 2023. These are: • NICE. Endoscopic ultra-sound guided biliary drainage for biliary obstruction. Interventional procedures guidance [IPG761]. April 2023 available at Overview | Endoscopic ultrasound-guided biliary drainage for biliary obstruction | Guidance | NICE • NICE. Endoscopic ultra-sound guided gallbladder drainage for acute cholecystitis when surgery is not an option. Interventional procedures guidance [IPG764]. June 2023 available at Overview | Endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis when surgery is not an option | Guidance | NICE	1	Agreed and noted. Specification has been amended with this inclusion.

Comments on the Equality and Health Impact Assessment		
There is a list of percentages in the Age section that is inconsistent. The percentages given are only partial and need clarification ie Pancreatitis/bile duct___%, aged ___; Hepatitis/Liver disease ___%, aged	1	EHIA has been updated. Noted, thank you. The EHIA has been amended to clarify that there are no routinely available data sources published that report morbidity and/or mortality from bile duct disease or pancreatitis either in total numbers, rates and percentages or broken down by age group. Noted, thank you.
I have questions with relate to Race and Ethnicity. There are only estimates of alcohol use and obesity available and estimates on viral hepatitis too. (Ethnic group) but this paper was first written in 2013 and equality was around then so why are there no studies?	1	In relation to estimates of viral hepatitis, as part of the Government's commitment to the WHO Elimination strategy to eliminate new transmission of viral hepatitis by 2030, statistics are routinely published about incidence and prevalence. Since this original EHIA was produced, new data has been published which does include viral hepatitis prevalence by age and ethnicity. The EHIA has been updated.
There is a lot of information relating to equal opps and safe guarding but little about training staff to educate sufferers. Those that are of refugee status, will they be entitled to help/ care if they fall ill with LD/CP? This is a potential grey area.	4	In relation to training staff to educate sufferers, prevention in all forms, including secondary prevention to reduce the likelihood of disease progression, is not within the remit of this EHIA as that will form part of an individual's care plan. In relation to refugees and asylum seekers, GP and nurse consultations in primary care, treatment provided by a GP and other primary care services are free of charge to all whether registering with a GP as an NHS patient, or accessing NHS services as a temporary patient. A temporary patient is someone who is in the area for more than 24 hours and less than 3 months.

		For secondary care services, the UK's healthcare system is residence-based. This means that you must be living lawfully in the UK on a properly settled basis to be entitled to free healthcare. Groups that are exempt from charge include: • refugees (people who have been granted asylum, humanitarian protection or temporary protection under the immigration rules) and their dependants • asylum seekers (people applying for asylum, humanitarian protection or temporary protection whose claims, including appeals, have not yet been determined) and their dependants • people receiving support under section 95 of the Immigration and Asylum Act 1999 from the Home Office Source: https://www.gov.uk/guidance/nhs-entitlements-migrant-health-guide
I do not feel this document highlights that the areas you are looking at relate to more self induced causes of Liver disease (LD), and Chronic Pancreatitis (CP), so it does come across as very negative in relation to those it is trying to treat. It is only when one realises that it [is] part of the whole, that it makes more sense, perhaps if it had been mentioned in the proposal brief it would have been clearer for those coming to it new.	4	Noted. This is intended for a commissioner and clinical audience, and the SWG recognises that this might need additional information for a lay reader.
Most people present with AP (Acute Pancreatitis) before CP is diagnosed and many doctors/specialists seem to step back from diagnosing CP if they have no exact cause (in my opinion). Whilst there is an importance of diagnosing correctly there is a part of the document that states only 5% of CP has been diagnosed with a cause and the rest is of unknown aetiology. (In Disability section).	2	No amendments needed.