Engagement Report for Service Specifications

Policy Reference Number	A02/S(HSS)/a
Policy Title	Liver Transplantation service (Adults)
Accountable Commissioner	Sarah Watson
Clinical Reference Group	Hepatobiliary and Pancreas
What stakeholders were contacted to be involved in service specification development?	CRGs stakeholders. The CRG membership includes representation from the British Liver Trust and the British Association of the Study of the Liver. The specification was also shared with NHS BT's liver transplant lead, NHSBT's Liver Advisory Group and the British Liver Transplant Group.
What stakeholders have actually been involved? State reason for any difference from previous question	As above
How have the stakeholders been involved? What engagement methods have been used?	Discussion and circulation of the specification for comment and consideration at expert meetings.
What has happened or changed as a result of their input?	CRG members have either made changes to the specification to reflect the comments and suggestions proposed or responded to the stakeholders to answer specific questions or comment further. There was quite a lot of

	updating of references and data. From the patient groups there was a greater drawing out of issues focussing on patient experience. The service specification remains broadly as published by the NSCT prior to April 2013 including relevant updates. The specification currently published on the NHS England website related only to live liver donation.
How are stakeholders been informed of progress with service specification development as a result of their input?	Comments are returned to stakeholders generally confirming what action had been taken or picking up any further points of clarity to be addressed.
What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement? (see Appendix One)	Level 3 - 6 weeks public consultation in line with the recommended level of consultation for all HSS that have not previously been included in a public consultation.

Appendix One

1. When do we need to consult and how long for?

The levels below describe a consultation period and engagement activity while a consultation is live. The levels should reflect an approach that is proportionate to the needs of the policy being consulted on. The levels described are based on the assumption of a robust period of stakeholder engagement that can be well evidenced in the policy development process.

Level 1	minor changes – no further consultation
Level 2	medium changes that are broadly supported by stakeholders through prior engagement - up to 6 week consultation, limited engagement activity during the live consultation
Level 3	significant changes that are broadly supported by stakeholders through prior engagement - up to 10 weeks consultation to include some proactive engagement activities during the live consultation period
Level 4	Significant change with some contentious aspects 12 week consultation to include some proactive engagement activities during the live consultation period
Level 5	highly contentious/ high volume impact on numbers of stakeholders/ high levels of dissent/ high financial implications/ high media or political profile = 12 week consultation plus an extensive range of pre and during engagement activity

NOTE: there may be exceptional operational or legal reasons that a formal consultation might be implemented outside of this framework.

2. Developing criteria for what we mean by proportionate

A series of prompt questions can help to identify the length and level of public engagement:

- How significant is the change for patients?
- Are certain patient groups disproportionately impacted?

- What is the size of the population group affected?
- What is the financial impact and affordability of the proposed change?
- Will the policy change the geography of where the services are provided?
- Is the patient group very small – can they be contacted individually?
- Has an Equality and Diversity impact assessment been done? What does this say?

3. Calculation tool to aid decision-making about consultation periods

Target audience	*Count*	*Significance of changes*	*Count*
• Public and all patients	4	• High levels of change • Changes are contentious • High public profile • Political interest	4
• Specialist patient groups (<1000) • Patients experience health inequalities in relation to these changes	3	• Medium to large number of changes • Consensus is not likely between stakeholders	3
• Specialist patient groups (<1000)	2	• Small changes • Consensus of support has already been established	1

Target audience + significance of change = total score.

- A score of more than 6 indicates that a level 4 or 5 consultation should be used
- A score of 5 or 6 indicates that consideration should be given to a level 3 consultation
- A score of 4 indicates that consideration should be given to a level 2 consultation
- A score of 3 or less indicates that consideration should be given to a level 1 consultation

Appendix Two – Stakeholder Feedback

Organisation Responding	Feedback Received	CRG response	Resulting Action
LD Janssen Pharmaceuticals	The statement in the 'Transplant listing' section: 'Patients listed with a diagnosis of HCV must have access to anti-viral therapy (AVT) based on the use of Pegylated Interferon in combination with Ribavirin (Peg/Riba). These new AVTs include Direct Antiviral agents (DAAs). This consists of therapy with the NS3/4A Protease Inhibitors Boceprevir or Telaprevir added to Pegylated Interferon and Ribavirin. An alternative regime of an NS5A inhibitor plus a Polymerase inhibitor, given for only 3 months' is very specific and may be interpreted as precluding the use of treatment options such as protease inhibitors other than telaprevir and boceprevir	To seek advice from clinicians & pharmacy leads on whether a generic statement would be more appropriate – ie "in line with NHS England policy" or if more clinical detail is necessary but could reference the group of drugs rather than brand names. SM British Society of Gastroenterology	More general statement include in spec
British Society of Gastroenterology	These changes appear fit for purpose.	Noted	No change necessary
British Liver Trust Nurses Forum	Re Outcomes Page 6 Use of a validated standardised (across all transplant and outreach centres) of a quality of life questionnaire for patients: At time of transplant assessment At intervals on the transplant list of 1mth, 3mthly and 6 mthly Post transplant at 6 mths and 1 year This would capture measurable outcomes for	Further discussions will be held at the annual audit days when QoL audit is reported by services.	Audit of patient outcomes is service requirement, specified in section 5.1. Section 6 describes a subset of outcome reports. It is expected that QoL measurements will be audited by services

	meeting domains 2,3 and 4.		over time.
Dr CW and Dr M W Liaison Psychiatry Service, Hospital Trust	In its current form, the specifications do not accurately account for the impact of psychosocial issues in the whole patient pathway. Psychosocial aspects of transplant may include: • pre-transplant assessment – screening for including co-morbid issues including depression • criteria for selection • transplant follow-up (early and late) Addressing the psychosocial needs of transplant patients improves outcomes and needs to be considered integral to the patient pathway. Neglect is a false economy.	To include statement about the relationship between the HSS specification / service and psychosocial aspects and services – needs to be accurate in terms of which elements are specialised and within NHS England's remit.	Changes reflected in specification
Novartis Pharmaceuticals	Page 6: Domain 5 'Appropriate immunosuppression in accordance with NICE guidance and effective monitoring and treatment to minimize the risks of adverse effects of immunosuppressive treatment.' We are not aware of any existing NICE guidance on immunosuppression. Page 9: Surgical Staffing. Some centres may find it difficult to achieve the number of 5 consultants. Page 12: The NHS England Manual for Prescribed Services (November 2012) states in section 16 'commissions the following drugs/devices: immunosuppression drugs prescribed following liver transplantation. (To note additional advice is being sought on	Noted This has been a long standing requirement on centres Agreed	No action No action Redrafted manual does not specify drug regime. Specification updated, see section on transplant listing page 13.

	drug policies relevant to this specification.)' Section 16 of the Manual refers to Adult Specialist Renal Services not Liver. We cannot fully review this specification until these drug policies are shared and this may alter the duration of consultation which is required. Page 13: Access to a nephrology services – 'if renal dysfunction is diagnosed - and a clinical psychologist when appropriate is considered essential. The routes to access social work and other support services will be offered to those patients requiring them.' – This sentence requires rewording.	Agreed	Specification updated
Consultant Gastroenterologist	The specification is very focussed around the transplant centres but due to the geography of these patients often find travelling very difficult. Has consideration been given to satellite units (hospitals where there are dedicated hepatologisits but are not transplant centres) in respect of follow up for immunosuppressive monitoring and initial work up investigations according to defined protocols. One could have a specification for such units and in reality this is what currently happens with pts often alternating review appointments between the transplant centre and local hospital with dedicated hepatologists. Currently there is a significant duplication of investigations as part of the transplant work up with many tests done locally and then rpt as part of the OLT work	For further discussion at Transplant services should work closely with centres local to the patient to share care and minimise travel to centres where possible, with the use of outreach wherever practicable.	No changes made to the service specification.

	up - the use of a hub and spoke concept with identified local units may prevent this.		