Appendix 1 – Stakeholder engagement feedback

Title of service specification: Specialist services for haemophilia and related bleeding disorders (adults and children)

Unique reference number (URN) -

The table below provides examples of stakeholder feedback excluding responses which were simply positive and supportive of the revised specification.

See embedded document on final page for the full stakeholder responses and SWG responses.

Organisation responding	Feedback received	SWG response	Resulting action
Clinician, Director of a haemophilia centre	These are welcome updates to the previous specification. However, there is a difference current provision of psychology, social worker, physiotherapy and data management services between centres. Therefore for some organisations there may be a need for an uplift in funding to deliver these to an adequate standard, whilst for others it may require greater scrutiny of how existing funding is used.	Thank you; note that there are subtle differences between things which are a 'must' deliver and those which are a 'should' deliver. It is the view of the SWG that the majority of services are in a position to deliver the 'must' components, the 'should' components, such as 'social worker' are aspirational. The spec does not state any sort of quantity, either in absolute terms or 'per service user' basis, although the respective professional groups may state (non-mandatory) preferred or target staffing levels or ratios. We agree that some services might require modest investment from existing expenditure; scrutiny of provision of services is undertaken by	No changes

		regional Spec Comm teams, for which an updated Haemophilia Dashboard will assist.	
	I consider that the updates support these objectives. However, there will need to robust monitoring arrangements in place for provider organisations, and actions take to address any problems identified.	Thank you. The SWG agrees with this response; Haemophilia service contracts are managed by regional Spec Comm teams, which make use of service dashboards and other nationally collated data for an oversight of services.	
	Yes, provided organisations contracted to provide services faithfully adhere to the specification and are challenged where they do not.	Thank you. The SWG agrees with this response and also wishes to see robust contractual oversight of haemophilia services.	
	One would hope there would be an improvement in patient access to social worker, psychology and physiotherapy services.	It is the intention of the SWG that the specification will improve access to a range of sub-services and healthcare professionals to support a more holistic approach to health and wellbeing for service users.	
Patient organisation	Would like to see occupational therapy moved from 'linked in' to being part of inhouse MDT at CCC. It has been my experience that psychology support has been limited to inquiry related issues, I would like to see the psychology service specification expanded specifically to include all mental health issues related to a bleeding disorder and it may also be appropriate to expand this care to guardians and caregivers who certainly experience psychological trauma as a consequence of bleeding disorders despite not being patients themselves.	Occupational Therapy: Thank you. The SWG shares your ambitions but must balance ambition with realism. In respect of occupational therapy (OT), it seems that most services are a long way from being able to establish OT as part of the Haemophilia MDT, however the SWG sees this as the start of that journey by recognising a role for OT in Haemophilia (and related) care for the first time. Psychology: The SWG shares your ambitions in respect of psychology support for Haemophilia and related conditions. The SWG has taken a bold step of making psychology a 'must do' component of care	UKHCDO Standards for emergency care explicitly referenced in section 7.9.

	Would like to see social work role, and possibly general role of CCC, to include collaboration with VCSE sector to promote patient wellbeing, for example working with UKHS. Other services for co-coordinated care very woolly. I have always believed there should be named individuals in other specialties who provide care to people with bleeding disorders, as it generally is better to concentrate bleeding disorder expertise if possible. I would suggest updating the specification here to have line, 'CCCs should form effective partnerships with other medical specialties including having a named consultant in other specialties who have a special interest in bleeding disorders'. -Another area also missing is emergency care, many hemophiliacs experience delays in treatment when attending ED for emergency care. We need something in this specification which addresses this. A line such as 'CCCs should coordinate with local emergency departments and ensure they have a supply of factor VIII and factor IX products. Administration of clotting factor products to a bleeding person with a bleeding disorder should never be delayed. Another option for this would be to issue all patients with a bleeding management plan so that if they attend an Emergency Department, the non-expert staff there know what to do.	and expects that this provision will evolve over time, under the leadership of the Haemophilia Psychology Association, to become the comprehensive psychology service that service users need. In the short term, it is likely that the focus of psychology support will be within the context of the infected blood products scandal. The SWG feels that it is aligned with the respondent on this issue. Social Workers: The SWG welcomes this suggestion. The SWG feels that this level of detail is beyond the scope of that required for a service specification, however we would expect Social Work involvement with haemophilia (and related) services to grow as a consequence of the new specification, and for this to evolve in the manner described. The SWG feels that it is aligned with the respondent on this issue. Named specialists: The SWG recognises the benefits of the suggested action but feels this level of detail is beyond the scope of a service specification. However individual trusts or local health economies may wish to implement such guidance, which would apply. In addition, if this becomes a national recommendation then this would apply equally alongside the specification. Emergency care: The specification cross-references UKHCDO standards for emergency care and these are now explicitly	

		referenced in section 7.9, and we hope to be able to update this with a new version before the specification is published. This detail concerning emergency care would be better placed in the UKHCDO standards/guideline. The specification is for the provision of haemophilia (and related) services which is, necessarily, focused on the non-emergency department provision. Summary: The SWG is grateful for the comments received and generally shares the views and ambitions of the respondent. The SWG feels that no changes to the specification are warranted for the reasons outlined.	
Haemophilia care provider	Some specification of expecting staffing ratios would be helpful to give weight to requests for additional staffing within NHS trusts	Whilst the SWG is sympathetic to this request it is beyond the scope of a service spec to quantify staffing levels or ratios. There are pros and cons of such an approach and currently the balance favours not quantifying or stating thus. However the spec does link to documents from other professional organisations and they may state or otherwise advise on what they consider to be appropriate staffing levels or ratios, although these figures would not be mandatory. The SWG would expect regional commissioning teams to intervene if information became available to indicate that service users were not receiving adequate care as described in the service spec.	No changes

	Not mentioned emergency department care particularly	Thank you. The SWG has considered your response and we have made a small clarification to the emergency presentation of bleeding disorders including haemophilia, still with cross-reference to the UKHCDO standards of care which are also now added to the 'links to other key documents' section.	Small change to emergency presentation, and cross-ref UKHCDO standards
	Our HCCC runs with 2 co-directors; a Consultant and a Specialist. Both have expertise in bleeding disorders and work at the same competence level. A Specialist is a SAS grade (see BMA website for further information https://www.bma.org.uk/our-campaigns/sas-campaigns) which works at an equivalent level to a Consultant. I therefore feel that the wording used negatively impacts on this and would encourage re-wording of this, such as 'Haematologist who specialises in Haemophilia and bleeding disorders'	Thank you. The SWG agrees with this response and has amended the specification accordingly.	Service users must be under the care of a haematology specialist with expertise and an interest in haemostasis and bleeding disorders.
Professional organisation	1. Service aims are written in a very broad scope and paternalistic fashion. (a) The previous specifications had patient empowerment (To ensure patients are involved in decisions about their treatment and engaged in service developments and improvements; To provide an environment in which patients (and their parents/carers where appropriate) are able to make informed decisions about treatment and are enabled to become independent throughout their lifetime, thereby minimising disruption to education, work and social activities) and	Thank you for your responses. In respect of (a) the SWG has reviewed the specification and does not agree with the sentiments. In respect of patient empowerment, note that the specification does reference 2 important sources and services will be held to account against these guidelines, see "Shared decision making, NICE guideline [NG197], June 2021" and "Supported self-management, summary guide. NHS England, 2020". In respect of (b), the SWG has sought to achieve a balance between a higher	

	individualised care (To ensure that the care of patients is individualised and conforms to national clinical guidelines and is monitored by objective external clinical audit). (b) The scope is open to interpretation and will impact on the standards developed for the peer review.	degree of specificity and being so broad that unintended conditions or diseases are included. The SWG has reviewed the scope of the draft specification has concluded that the scope has the correct balance in these respects.	
	The change in recommendation for psychological from should to must is welcome and supportive of MDT care. We also welcome the inclusion of the UKHCDO Peer review. If a provider is not reviewed or has not sought a review, will the commissioners stop the service provision? If the centre is a smaller centre, the responsibilities of the commissioner, nearest CCC, and trust management to enable safe care are not detailed.	Thank you for this response. If a provider wilfully opts out of, or otherwise obstructs, the UKHCDO peer review process then the local responsible commissioner will be expected to inquire and challenge the provider on this aspect of the specification. In respect of the relationship between HC and their 'linked' CCC, the specification does support informal network arrangements, see section 7.3 and other parts of the draft specification. The commissioner responsibilities are for the whole specification including any cross-referenced or linked external sources, on this basis it does not need to be explicitly stated. Trust management teams have separately held responsibilities to ensure patient care, including for the users of services for haemophilia and similar. On this basis it is beyond the scope of this service specification to explicitly cover these points.	
	It will promote the development and delivery of services for patients with severe bleeding disorders to some extent by increasing the support for physiotherapy and psychological services.	Thank you for your responses. The SWG agrees with the sentiments of these responses however the specification has been written in a manner to apply to all locations which do vary substantially in their	

	Women with Heavy menstrual bleeding have particular challenges in accessing care and are counselled on treatment choices. There is mention of a care plan, but there is no mention of the need for combined services. Access to gynaecology is a must rather than a should, and the most appropriate setting is a combined or joint clinic.	scale and access to support services such as gynaecology. On this basis the the SWG has attempted to strike a balance between a realistically achievable specification which all providers can achieve and an ambition to ensure services are evolving and improving for patients. The SWG considers that this balance is broadly correct and affords a degree of flexibility in how those services are delivered.	
	Page 3: Scope - platelet function defect. Page 4: add including training for intravenous infusions and use of portacaths in the paragraph on outreach Page 3: Diagnosis and referral - remove especially in their relatives. Page 5: Access to insertion rather than siting Page 5: We propose retaining the sentence from the previous specification. 'Severe patients must have 6 monthly reviews, and small children (<5 years) must be seen 3-4 times per year'. Efforts should be made to offer in-person reviews twice a year, and this may not be achievable in all instances. Page 5: 'Services must be sensitive to the referral pathway by which the service user received their diagnosis; this can sometimes create barriers from the service user and significant others, which must be handled sensitively' The sentence is dense, and expectations of services unclear.	Amendments accepted and implemented unless stated otherwise here: Paediatric review: The specification has been intentionally written to reduce the burden of review on paediatric patients and encourage services to tailor this to individual patients, with a minimum frequency. The SWG feels that the specification wording is broadly consistent with the recommended amendment and has therefore opted to change the text. Sensitivities: The SWG reflected on this comment and concluded that the sentence itself does not contribute to the specification, consequently it has been removed. Self-referral: Thank you for this comment, the SWG has reflected and updated the specification to reflect the referral pathway sometimes utilised by relatives of service users, which is a form of self-referral for those individuals. Networks: The intention of the specification is to promote informal clinical networks centred	Various minor changes to spec as detailed in adjacent cell.

	7.2 Familial case tracking should also include scope for self-referral. 7.3 The first statement is ambiguous: 'The Provider is required to participate in a networked model of care '. Further, in the event of a network model of care, the governance arrangements have not been elaborated. 7.5 Lab section is redundancy and can be shorter 7.9 There are standalone UKHCDO guidelines that are not endorsed by BSH and are available on the UKHCDO website. It has not been mentioned as a guideline resource.	around a CCC. However this is not a mandatory component hence it is presented as a 'should' component, in addition such networks will emerge organically and may need to change over time, so the choice of words in this section is intentional. Laboratories: The section on laboratories consists of 3 paragraphs and 216 words; this section has already been substantially reduced from the current specification. Without more specific comments the SWG is unable to implement this recommendation. Guidelines: The specification is not intended to serve as a comprehensive repository for guideline documents, the SWG is confident that all specialists so referred to in the specification will be familiar with the guidelines or otherwise know where to located them. The specification does reference some of the more important or non-haematology specific documents.	
Professional Organisation (continued)	Challenges 1. specialist care e.g. Dental care. Only a limited number of hospitals provide special needs dentistry, and Haemophilia is not listed under special needs dentistry as an indication. As such there is a reluctance to see out-of-area referrals with no funding mechanisms in place. 2. Other services for coordinated care are brief and open to interpretation. Difficult to negotiate with managers locally to set up new pathways.	Dental: It is beyond the scope of the specification to address funding mechanisms. The SWG generally shares these concerns and encourages specific examples to be raised with local specialised commissioning teams. Other services: The focus of the specification is on the haemophilia and related services. How these engage and link with other services to provide care for the service user group will vary between organisations and	No changes

		therefore it is beyond the scope of the specification to dwell on these aspects in any significant detail. The SWG hopes that inclusion of the specialities within the specification will promote co-ordinated care within and across organisations and all parties, including managers. Summary: No changes to these sections are warranted.	
	Sex: the current wording is complex and unclear. Suggestions included 'Some of the inherited bleeding disorders, including the most common severe bleeding disorder (haemophilia A and B) are X linked and seen mostly in men. Other bleeding disorders are seen in both men and women, but women may be more symptomatic because of menstrual bleeding. Under impact assessment we expect the following to be affected. Younger children may be disadvantaged due to the later license of products, and this will become critical when the licensed product is potentially the only effective or the first effective treatment for a condition. No mitigation provided Homeless people are affected as they are unable to store the treatment that needs to be given regularly, either on a weekly or bi-weekly basis. Agree with Mitigation, but need social support as well. People with addiction struggle with compliance and, again, require more social support and	The SWG is grateful for the comments provided concerning the EHIA. The first comment is an editorial change and does not constitute a material change therefore the SWG has opted not to amend the EHIA. The other comments are helpful, however the SWG has concluded that these relate to specific issues of medicines management and do not relate more generally to the applicability of the service specification. Therefore the SWG has opted not to amend the EHIA. In respect of the health literacy comments, the SWG is of the view that these are addressed under the 'recommendation' component of the EHIA where services are expected to make adjustments for service users depending on their level of understanding.	

	different treatment regimens, including more contact. Patients with poor literacy or health literacy are less likely to seek services. Refugees - similar problems as homeless people.		
Pharmaceutical company	While we value the enhancements and additional clarity in the role of physiotherapists within the proposed updates, CSL Behring feel it would be important to consider encouraging use of specialised equipment such as ultrasound machines to explore sub-clinical bleeds in at risk patients. The concern around sub-clinical or silent bleeds has come up in advisory board discussions with clinicians as well as with Haemophilia Chartered Physiotherapists Association (HCPA) stakeholder interactions. It is also documented in several scientific publications. Regarding the access to Gene Therapy (Section 7.2), we feel that it would be helpful to make eligible service users aware of the option of ATMPs once available, potentially in collaboration with patient organisations, to ensure equity in access across the UK. We would recommend the Specification to highlight the need for spoke centres to set up an agreed referral process with their local, appropriate, hub centre and to ensure that this process is suitable for the referrals for ATMPs.	Sub-clinical bleeds: The SWG recognises the increasing use of ultra-sound scans and similar in the management of bleeding disorders; the SWG expects this aspect of care to be covered in guidance, or similar, from the HCPA which is in turn cross-referenced in the specification. The SWG does not feel that this level of detail is warranted in the service specification. Gene therapy awareness: The SWG agrees with this sentiment but feel it is not necessary to include this level of detail in the specification. Separate activities from multiple parties are expected to raise awareness of gene therapies for haemophilia patients in the NHS. Gene therapy referrals: This level of detail will be included, and addressed, in the cross-referenced UKHCDO guideline on the management of Gene Therapies in Haemophilia. Gene therapy documents: The UKHCDO Guidelines are cross-referenced in section 7.2 but are not included as a key document informing the specification as they relate to one, nascent and potentially niche component	No changes

	This could be detailed after the following paragraph: 'Service users who may be eligible for advanced therapeutic medicinal products (ATMPs) such as gene therapy for haemophilia A and B, will be managed through CCCs in a hub and spoke network.' We expect additional key documents to be published in relation to the delivery of gene therapy in the UK. CSL Behring would encourage the inclusion of these documents within the Service Specification: - the NHS invitation to tender, to commission haemophilia Advanced Therapy Medicinal Product (ATMP) treatment hubs - the UKHCDO guidelines (currently included in paragraph 7.2 but not in 7.9.)	of the care pathway. This will be reviewed for future amendments to the specification. NHS Tender documents are not considered appropriate for inclusion or reference within an NHS England service specification.	
Patient organisation	There is an important section of the service specification which is the provision of psychological support for children and families which is missing. We know from experience that early memories of trauma whether due to phobia, pain as examples can become embedded and have long lasting negative impacts on a person as child and then adult to build trust with their healthcare team and engage fully with the management of their condition. There is a needed for psychologist support in this area but also a need for mental health professionals including, mental health nurses, or social workers who are trained in mental health	Psychology support: The SWG feels that the level of detail suggested is beyond the scope of what is required for a service specification. Note that sources of information from the HPA is cross-referenced and this source could contain the sort of details, and more, stated by the respondent. By extension this would fall within the remit of the specification. Psychological and mental health: The SWG is in agreement with the respondent and for this reason has specifically listed psychology as a 'must' do component of the service specification. Long term plan: The SWG feels that the new specification, especially in respect of	No changes

	to be involved in the care pathway in paediatric care. We feel it is vital that psychological support for adults and children are embedded in the service. The links below highlight the NHS plan to increase mental health support for children and those living with a long-term condition. In addition, there is another paper called 'no health without mental health' that highlights the importance of mental health physical health professionals working together. Whilst this is older it influences the NHS long term plan and the mental health five year forward. Mental health five year forward https://www.england.nhs.uk/mental-health/adults/nhs-talking-therapies/mus/ Long term plan https://www.longtermplan.nhs.uk/areas-of-work/mental-health/ No health without mental health https://www.gov.uk/government/publications/no-health-without-mental-health-a-cross-government-outcomes-strategy	prominence of psychological health for haemophilia (and related) patients is consistent with the examples provided by the respondent. It would be beyond the scope of the specification to include all of these examples, and the specification defers to the HPA to ensure these components are implemented or adhered to.	
	In Outcomes 6.2 Measures of functional joint damage and Activities of Daily Living as recommended by the Haemophilia Chartered Physiotherapist's Association (HCPA)	The SWG shares the respondents concerns about access to and availability of physiotherapy/ists for haemophilia and related conditions. The SWG hopes that the prominence of physiotherapy within the	

	This tends to only happen for severe haemophilia and other severe BDs so would those with a other BD's be measured in a different way or would physiotherapy be available for all BD's. This could be a negative impact if a process to measure outcomes was not available. There is already a severe shortage of physiotherapists across the service.	specification will help, in part, to address this gap. Note that the specification states that physiotherapy is a 'must' do component of the service. In addition, the specification cross-references, and by extension defers to, recommendations from the HCPA; recommendations or advice on specific assessment tools would be best addressed separately by the HCPA.	
Pharmaceutical company	1) 6.2 Service defined outcomes/outputs: Would there be value in specifying what the "other types of bleeds" are to support the understanding of those stakeholders who don't specialise in bleeding disorders? 2) 7.9 Links to other key documents: Where the list of current clinical policies as of August 2023 sits, would it be helpful to have a direct link to an up-to-date list of clinical policies? https://www.england.nhs.uk/commissioning/spec-services/npc-crg/blood-and-infection-group-f/specialised-blood-disorders/	Other bleed types: These are by default all non-joint bleeds. To provide an exhaustive or extensive list of other bleed types is beyond the scope of the specification and could make the document unwieldy. Policy links: The suggestion is welcome and has some merit. However the specification is not intended to serve as a definitive or primary reference to guidelines or policies. In addition, the SWG cannot be sure that the currently online hosting of the clinical commissioning policies will remain thus so has preferred not to state this link.	No changes

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