

Engagement Report for Service Specifications

Unique Reference Number	1737
Specification Title	Proton Beam Therapy (All Ages)
Lead Commissioner	Iain Mellis
Clinical Reference Group	Radiotherapy CRG
Which stakeholders were contacted to be involved in service specification development?	<p>Stakeholders of Radiotherapy and Children's & Young People's CRG plus individuals or representatives from:</p> <p>Newcastle University, Cancer Research UK, Brain Tumour Action, Brain Tumour UK, The Brain Tumour Charity, Teenage Cancer Trust, Children with Cancer, Macmillan Cancer Support, ClicSargent , Prostate cancer UK, Gray Institute for Radiation, Oncology and Biology; Caudwell Trust, ESTRO - European Society for Radiotherapy and Oncology, Society and College of Radiographers, Children's Cancer & Leukaemia Group, Society and College of Radiographers, Royal College of Radiologists, National Cancer Research Institute, National Institute for Health and Clinical Excellence (NICE), Clatterbridge Cancer Centre NHS Foundation Trust, National Cancer Intelligence Network (NCIN), PROS (Paediatric Radiation & Oncology Society), Medical Research Council, The Paul Scherrer Institute, PSI, Institute of Physics and Engineering in Medicine (IPEM), Lay representative, Liverpool University, NCRI, Oxford University, Birmingham NHS FT, Oxford University, Cambridge University, Birmingham NHS FT Manchester University, Science and Technology, Institute of Cancer Research, St James Teaching Hospital, Oxford University</p>

	<p>Hospitals, North Bristol NHS Trust, MIPPR, Chief Allied Health Professionals, Chief Allied Health Professionals , Health Education England, Kings College London.</p> <p>NHS Scotland, NHS Wales, Health & Social Care Board (Northern Ireland)</p>
<p>Identify the relevant Royal College or Professional Society to the specification and indicate how they have been involved</p>	<p>Society and College of Radiographers Royal College of Radiologists</p> <p>Through stakeholder testing.</p> <p>Both organisations have been involved in the National PBT Programme with regards to workforce planning.</p>
<p>Which stakeholders have actually been involved?</p>	<p>All of the above</p>
<p>Explain reason if there is any difference from previous question</p>	<p>Not Applicable</p>
<p>Identify any particular stakeholder organisations that may be key to the specification development that you have approached that have yet to be engaged. Indicate why?</p>	<p>Not to my understanding</p>
<p>How have stakeholders</p>	<p>Stakeholder testing as per NHS England governance.</p>

<p>been involved? What engagement methods have been used?</p>	<p>Some stakeholders have been involved in and contributed to the National PBT Programme at various stages over a number of years This ranges from direct involvement and support to providing advice and 'consultation'.</p>
<p>What has happened or changed as a result of their input?</p>	<p>The National PBT Programme and service has and will continue to develop over a number of years. This has been from competitive selection of providers to development of care pathways and treatment models. Stakeholders have played various key roles in each of the stages of the service development</p>
<p>How are stakeholders being kept informed of progress with specification development as a result of their input?</p>	<p>Mostly through the CRG and National PBT Programme structure which has comprehensive membership and good participation from allied organisations</p>
<p>What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement?</p>	<p>Stakeholder testing recommended 6 weeks public consultation was required.</p>

Stakeholder/CRG Feedback



Organisation Responding	Cons period	Feedback Received	PWG response	Resulting Action
The Royal College of Radiologists (RCR)	12 weeks	<p>The RCR asks that NHS England considers the following points:</p> <p>(a) There is a lack of explicit reference in the draft specification to the fact that the overseas programme will need to continue for a period of time during the ramp up phase for UKPBT treating centres and probably beyond this</p> <p>(b) There is a lack of clarity about expanding eligibility for PBT, especially for adult indications</p> <p>(c) There is a lack of clarity about how referrals will be managed to the UKPBT centres, both initially and how direct referrals will be managed at a later date, including how time to treatment will be monitored, both for CWT but also to reassure referrers of timeliness of pathways</p> <p>(d) The service specification states that patients should be referred from an appropriate site specialist MDT to the site specialist proton MDT. The RCR</p>	<p><i>Not relevant to this service specification. Is included in impact assessment</i></p> <p><i>Not relevant to service specification. Clinical commissioning policies are separate issue</i></p> <p><i>Referral pathway included</i> <i>Monitoring of times – clinical outcome #110</i></p> <p><i>Section on MDT lifted from Radiotherapy</i></p>	

		<p>suggests that the proton MDT be specifically designated as such. It should also be stated that all treating MDTs should be peer review compliant and all treating clinicians undertake treatment in areas only where they have sufficient expertise so to do (NHS best practice and RCR guidance)</p> <p>(e) There is a lack of clarity about the interdependencies needed, especially around sarcoma surgery (not mentioned as a specific group)</p> <p>(f) More robustness is required around the full meaning of “integrated service” in this specification – a list is provided but the depth of integration is not addressed</p> <p>(g) The RCR suggests that NHS England should review whether patients being treated should remain under the follow-up of the treating PBT centre as only the treating team can fully interpret long term toxicity in terms of dose prescribed / delivered and some views expressed that late side effects are not necessarily always correctly assigned to therapy</p> <p>(h) Further justification is required of the need for 2 treatment rooms – the main risk to treatment seems to lie with cyclotron failure which stops both rooms working rather than gantry failure which is relatively rapid to fix</p>	<p><i>service specification. RCR guidance on peer review to be included when published Sarcoma surgery added to section 2.2</i></p> <p><i>Section on integration lifted from radiotherapy service specification & included in section 2.2</i></p> <p><i>Service specification includes reference to follow-up. Exact model of follow-up to be confirmed once outcomes solution is finalised.</i></p> <p><i>Gantry ‘up time’ is estimated at 98%. Due to the complexity of equipment in the treatment rooms, it is more likely that the service will be disrupted by gantry/treatment room faults than cyclotron. Experience from overseas providers</i></p>	
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Association of Paediatric Anaesthetists of Great Britain and Ireland	6 weeks	<p>1. P1. The service specification describes the provision of Proton Beam service within England. This ignores the reality that children from the countries with devolved healthcare provision; Wales, Scotland and N Ireland, will inevitably be referred to their most local centre for treatment. This will result in a quantifiable cross-border flow and should be planned for within commissioning. This is some extent recognised within 3.1, p4.</p> <p>2. P1. Secondly, the prospect of a privately run organisation (http://www.proton-int.com/our-centres) establishing a service for children in S Wales should be acknowledged as a potential referral pathway for some children in the S and S west of England should they achieve the necessary standards for governance and service provision contained within GPAS 2017 (Guidance on the provision of paediatric anaesthesia services). (http://www.rcoa.ac.uk/node/25301)</p> <p>3. Pages 2 and 3. 2.2 and 2.3. Use of the term “trained paediatric anaesthetist”. There is no absolute definition of this term and we suggest that the phrase “appropriately trained and experienced anaesthetist” might better serve the commissioning process. Anaesthetic services for children should reflect the need to deliver the standards described in GPAS (see above hyperlink). This would include the clear requirement of any consultant anaesthetist who works with children to have completed the appropriate training and maintained the appropriate competencies to deliver a high standard of care in their described field of work i.e. to work in the specialist</p>	<p><i>Section 3.1 includes provision for devolved administrations</i></p> <p><i>This is a contracting/ procurement issue.</i></p> <p><i>A separate anaesthesia section has been included (2.4)</i></p>	

	<p>area of Proton Beam Therapy. Such anaesthetists should be competent to work with a wide range of ages 0-16(18) years, with children with significant comorbidities, who become progressively unwell over the course of treatment, in an isolated environment and inevitably with no immediately available adjacencies.</p> <p>4. P2, 2.2. Interdependence with other services. There are two glaring omissions within this clause. 1. There will need to be an SLA with the regional paediatric intensive care retrieval and transport service to ensure that should a child deteriorate and require critical care support then this is immediately available. This is absolutely integral to the delivery of such a PBT service in these remote locations. Secondly and in support of this there would need to be a service provided by consultant paediatricians, who would be available to attend to support the resuscitation and management of a deteriorating child should the need arise. Notionally this would be the on-call paediatrician from the local hospital, but will need to be explicit within these standards.</p> <p>5. It is important to recognise that the crux of these service standards is the delivery of anaesthetic services as described in GPAS 2017. And that this is equally applicable to services commissioned within the NHS or Private sector. It is important to commission services that can deliver the whole care pathway for children, of which anaesthesia is only one part and that similar competencies are required in staff who provide pre-anaesthetic assessment, ODPs assistance and recovery. There should be an experienced lead for any team delivering anaesthesia on these sites to ensure that all of these governance elements are met regarding staffing, equipment and environment. The responsibility for ensuring that these governance needs are met rest with the executive board of the Designated providers of the service, (Item 6, page 8).</p> <p>6. P7/8 5.1 and/or 5.2. Applicable national standards. Guidance on the provision of paediatric anaesthetic services should be included within this list.</p>	<p><i>Included in anaesthesia section National standards for paediatric services added to specification.</i></p> <p><i>Included in anaesthesia section</i></p>	
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		http://www.rcoa.ac.uk/node/25301	<i>Included in section 5</i>	
Children's Cancer and Leukaemia Group	6 weeks	<ul style="list-style-type: none"> Description section at start of document: 'The physical properties of protons results in almost no radiation dose being deposited in the normal tissue beyond the tumour' is overstated. PBT is still associated with long term toxicity of surrounding normal tissue although believed to be less than with conventional techniques. Monitoring for long term toxicities will be an important part of ongoing follow up and the associated toxicity of PBT shouldn't be seen as negligible. There appears to be no discussion as to the lack of trial evidence for the use of proton beam therapy nor any acknowledgment of the potential for pseudo progressive phenomena in the brain, we feel it is important to give a balanced view. I think it should be mentioned that there is some concern over the increased LET of protons compared to photons and that this in combination with the "dose dumping" phenomena associated with the Bragg peak physical properties can result in a challenge in cerebral tissue and has led in children to some USA centres reducing standard doses close to chiasm or even extending fields to avoid eloquent structures being vulnerable to such effects. In children in particular the standard doses in situations of LGG for example are needed to be carefully evaluated. 'The centre is registered with the CCLG' is not correct. The CCLG is a membership organisation for individuals, not centres. 'Professionals running the service should be members of the CCLG' is more appropriate. The devil is in the detail. Complexities in the treatment pathway will be significant. Resources will be needed for coordination – a coordinator for children and families in each PTF liaising with teams in PBT centres. The key clinical staff to plan, deliver and supervise PBT must have sufficient training and credentialing, and must have a sufficiently large 	<p><i>The description contained within the service specification is correct and does not need changing</i></p> <p><i>Section 3.4 amended to reflect inclusion of clinical trials and studies</i></p> <p><i>This has been removed</i></p> <p><i>Each patient will have a named key worker. Section 2.3 amended</i></p> <p><i>Word 'appropriately' added to trained in</i></p>	

	<p>volume of clinical practice to maintain their clinical experience to the highest possible standards in order to ensure best possible clinical outcomes. PBT is far more complex than conventional RT with a far more technical considerations which need to be integrated into high quality clinical decision making.</p> <ul style="list-style-type: none"> • Communication will need to be optimised in order to deliver RT and chemo on time, and existing 'pre-PBT' staffing unlikely to be sufficient. • Many RT patients are undergoing rehab and some need to remain as inpatients for this. Will there be capacity for patients to continue receiving inpatient rehab in PBT centres and continue while undergoing PBT if not fit to be discharged? If not, children needing rehab may not be able to have PBT. • For a commissioning document we would expect there to be at least some outlining even if brief of which patient groups that would be expected to be referred in the referral pathway schema. We are expecting the current criteria to be widened but these details are important in the consultation phase as there will be a variance of opinion. The details are sadly missing and these are vital to be laid out up front, these include strategies when time to radiation are vital and if protons are proscribed but unable to be delivered on time there needs to be some guidance in the document. • A comment on palliation (we believe it should be done locally) would be valuable. • The patients and the diagnoses covered by this consultation are 	<p><i>section 2.3</i></p> <p><i>Communication will be included in Joint Operational Policy for the PBT centres.</i></p> <p><i>Section 2.2 amended to include 'inpatient services'.</i></p> <p><i>Relevant clinical policies are referenced in the specification</i></p> <p><i>Understand this will be included in paediatric RT service specification to which this specification will refer.</i></p> <p><i>Guidance already</i></p>	
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		<p>generally very complex. It should be noted in the introduction that this document gives a high level outline of the service specification and much more detail sits behind it. It may be useful to reference the CCLG/SCOR/RCR Good practice guide for paediatric radiotherapy https://www.rcr.ac.uk/system/files/publication/field_publication_files/BFCO%2812%295_Good_practice_1.pdf</p> <p>Overall this is a carefully thought through, sensible and evidence-based description of the service specification. The patient group most likely to benefit from PBT are necessarily complicated, require multiprofessional and multidisciplinary support to optimise their treatment, and therefore this must be delivery in a hospital environment that has all the necessary expertise available.</p>	<i>included in section 5 & QIs</i>	
CLIC Sargent www.clicsargent.org.uk	Not clear	<ul style="list-style-type: none"> - There needs to be specific references included to teenagers and young adults (TYA), as their services and care are separate to that of children and adults. - The care pathway is missing specific reference to social care assessment and support. - The social care assessment should be done at an early stage and must be taken into account when assigning a centre. - There needs to be a definition for psychosocial support and indeed who will provide the assessment for support from allied health professionals. - There needs to be a reference to patient accommodation in the Facilities and Equipment section. Without suitable accommodation, many patients would not be able to access proton beam therapy without serious consequences on their immediate family. 	<p><i>Title to be amended to 'All ages' or Adult, TYA & Paediatric'</i></p> <p><i>Care pathway amended</i></p> <p><i>Care pathway amended</i></p> <p><i>Included in interdependencies</i></p> <p><i>Accommodation is referenced in 'Interdependence with other services'. Also added to Facilities &</i></p>	

		<ul style="list-style-type: none"> - There are a number of other gaps in the Facilities and Equipment section, including: consulting rooms (multi-use for nursing, medical and allied health professionals to communicate with families and or prepare children, young people or adults.); Play / recreational area (age related and considering needs of family and carers supporting patient); and waiting areas, with refreshment availability but separate area for children starved for general anaesthetics. - It is vital that play specialist reviews are included throughout the process, from the initial assessment right through treatment. Adequate assessment and planning by an experienced play specialist can help reduce the number of children requiring general anaesthetic and speed up proton beam therapy delivery times. It is also worth noting that some older children and adolescents with high levels of anxiety or any age with learning disabilities may also benefit from specialist play interventions. - Assessments and HNAs should be sent from the local CNS / Key Worker to the proton beam therapy centre and utilised throughout planning and treatment. This will assist the family from having to “tell their story” repeatedly to new faces, and will ensure children and young people have care planned that is sensitive to individual needs. - When thinking about co-location it is worth recognising that there is no paediatric intensive care at UCLH and therefore a pathway to another London Centre will be needed if a child has an anaesthetic problem. - On completion of treatment and referral back to the local PTC, the 	<p><i>Equipment</i></p> <p><i>Facilities and equipment section amended</i></p> <p><i>Included in care pathway</i></p> <p><i>All patients will have a key worker. Section 2.3 amended</i></p> <p><i>Both centres have existing established pathways with supporting children’s hospitals. Section 2.2 amended</i></p> <p><i>In QIs (#7)</i></p>	
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		<p>HNA should be updated and returned to the referring centre. This will save the family “telling their story of the proton beam therapy experience repeatedly” when they return to local care.</p> <ul style="list-style-type: none"> - Outcome data should include experience outcomes for children and young people that enable comparison of approaches for consistency across both centres - There should be an age-range definition for children who will have access to a paediatric anaesthetist. We recommend guidance is sought from paediatric anaesthetists / intensivists on age range with particular attention to upper limit. 	<p><i>PROMS included in QIs and outcome collection</i></p> <p><i>The working group disagree with this. An anaesthesia section has been added. It is anticipated that some TYA or Adult patients may need GA.</i></p>	
Alder Hey	6 weeks	<p>The patients and the diagnoses covered by this consultation are generally very complex. It should be noted in the introduction that this document gives a high level outline of the service specification and much more detail sits behind it. It may be useful to reference the CCLG/SCOR/RCR Good practice guide for paediatric radiotherapy.</p> <p>https://www.rcr.ac.uk/system/files/publication/field_publication_files/BFCO%2812%295_Good_practice_1.pdf</p>	<p><i>Included – see above.</i></p>	
Medical Research Council	6 weeks	No comments		
CYP Clinical reference group	6 weeks	Could Teenagers and Young Adults (TYA) be added to the proton beam service title (in addition to adults and children)	<p><i>Title to be amended to ‘All ages’ or Adult, TYA & Paediatric’</i></p>	

		<p>Section 2.1 does not include a social care and psychosocial care assessment that may enable children and young adults to feel supported and be able to take up treatment.</p> <p>In section 2.2 Interdependence with other services. The CRG feels that the PBT service should be integrated with Teenage and Young Adult Oncology (TYA) in addition to paediatric and adult oncology service. There should also be information regarding psychosocial needs, social care assessment documented at this stage and the patients should have a known key worker. Furthermore, education needs should be included in addition to play therapy.</p> <p>In Section 2.3, youth workers should be included. There should be both adult and paediatric nurses.</p> <p>In section 2.4 whilst the section on patient outcomes (203) specifies patient accommodation there is no reference to it in the Equipment and facilities section . This should be defined in this section as without suitable accommodation many would not be able to access PBT without serious consequences on their immediate family. The issue of accommodation and social care support needs to be referred to much more explicitly in the specification.</p>	<p><i>Care pathway amended</i></p> <p><i>Section 2.2 amended</i></p> <p><i>Youth Workers will be included in TYA oncology service</i></p> <p><i>Accommodation is referenced in 'Interdependence with other services'. Also added to Facilities & Equipment</i></p>	
Barts Health NHS Trust (Ind clinician)	Not clear	There is no mention of ophthalmology methodology. 10% of infants with cancer will have a tumour due to retinoblastoma. The technique necessary for PBT is slightly different.	<i>Clinical Commissioning policy issue</i>	
Society of Radiographers (ind response)	6 weeks	You have not defined domains 6 or 7	<i>Unclear what this refers to</i>	
General public	Not	I see this as a longed for enhancement to NHS England Specialised		

/Cancer survivor	clear	Commissioning's Portfolio of Radiotherapy equipment and the 2 hospitals chosen are the perfect choice as two of the Hospitals making up the NHS new models of Care National ACC Vanguard . Thanks for sending me this		
Nottingham University Hospitals NHS Trust (ind clinician)	6 weeks	<p>I think this is a very carefully thought through, sensible and evidence-based description of the service specification.</p> <p>My clinical experience tells me that the main patient group to benefit from PBT are necessarily complicated, require multiprofessional and multidisciplinary support to optimise their treatment and therefore this absolutely must be delivered in a hospital-based environment which has all the necessary expertise available.</p> <p>Secondly the key clinical staff to plan, deliver and supervise the therapy MUST have sufficient training and credentialing and MUST have a sufficiently large volume of clinical practice to maintain their clinical experience to the highest possible standards in order to ensure best possible clinical outcomes. PBT is far more complex than conventional photon-based radiotherapy with a far more technical considerations which need to be integrated into high quality clinical decision-making.</p>	<p><i>Section on MDT lifted from Radiotherapy service specification. RCR guidance on peer review to be included when published</i></p> <p><i>Word 'appropriately' added to trained in section 2.3</i></p>	
Rosemere cancer Centre (ind clinician)	6 weeks	<p>The document says there is a maximum of 1500 PBT patients annually across the whole country. This equates to approx. 3 patients per day per PBT centre. This seems a very low workload and I would recommend explaining why the workload is so low in more detail.</p> <p>Currently the document reads as though these extremely expensive and complex PBT centres are only treating very few patients.</p>	<p><i>1500 fractionated treatments with an average fraction number of 30 treatments. This is based on a 14hr working day in two centres with three rooms treating complex proton therapy. The modelling reflects the case mix and the equipment.</i></p>	

			<i>Numbers have been validated with international centres</i>	
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Draft for public consultation