

B01/S/a

**2013/14 NHS STANDARD CONTRACT  
FOR RADIOTHERAPY (ALL AGES)**

**SECTION B PART 1 - SERVICE SPECIFICATIONS**

<b>Service Specification No.</b>	B01/S/a
<b>Service</b>	Radiotherapy
<b>Commissioner Lead</b>	
<b>Provider Lead</b>	
<b>Period</b>	12 months
<b>Date of Review</b>	

**1. Population Needs**

**1.1 National/local context and evidence base**

Radiotherapy is the use of ionising radiation to kill cancer cells with the aim of cure or effective palliation. Radiotherapy is used in the treatment of over 40% of all patients who are cured of their cancer.

The National Radiotherapy Implementation Group (NRIG) is supporting local services to deliver these requirements, the detail of the national radiotherapy programme and in support of understanding radiotherapy can be found at <http://www.ncat.nhs.uk/our-work/ensuring-better-treatment/radiotherapy>

Improving Outcomes: A Strategy for Cancer (2011) sets out that

- “Access to radiotherapy is critical to improving outcomes and, to improve outcomes from radiotherapy, there must be equitable access to high quality, safe, timely, protocol-driven quality-controlled services focused around patients’ needs”.
- Detailed modelling suggests that 52% of cancer patients should receive radiotherapy as part of their treatment. In 2007, it was estimated that only 37% of cancer patients accessed this treatment. While radiotherapy capacity has increased, the demand has not increased at the rate previously predicted and there remain variations in activity across the country.

Improving Outcomes: A Strategy for Cancer also states that

- “Improved outcomes can also be delivered by ensuring that patients have access to high quality modern radiotherapy techniques, comparable to those used in other European countries, to improve cure rates and improve patients’

experience by minimising any long-term side effects of treatment”.

This specification focuses on radiotherapy for malignant disease. It is recognised that a small number of patients with benign conditions may also benefit from radiotherapy and this provision will also be governed by the same standards set out in this document.

The National Radiotherapy Advisory Group (NRAG) report published in 2007 set the standard for the provision of radiotherapy. The report estimated that 52% of all cancer patients could benefit from radiotherapy during their treatment. Currently uptake is closer to 38%. The NRAG report set out that demand for radiotherapy would be up to 54,000 fractions per million population by 2016. Rates of uptake for appropriate patients will be influenced by multidisciplinary team (MDT) practice, fractionation policy, brachytherapy usage and advanced disease (fewer fractions).

The Radiotherapy Clinical Information Group has recommended changing the currency from fractions to attendances (which encompass where a patient may receive more than one fraction in a visit). The relationship is approximately 0.87 attendances per fraction. A national modelling tool (Malthus) will enable each radiotherapy service to model the predicted demand based on local variations in cancer incidence and other patient related factors. It is a requirement that the national figure is locally assessed and locally enumerated using the Radiotherapy Malthus modelling tool published by the National Radiotherapy Implementation Group (NRIG). [www.camradiotherapy.org.uk/malthus](http://www.camradiotherapy.org.uk/malthus)

## 2. Scope

### 2.1 Aims and objectives of service

Using the Quality Dashboard approach it is expected that radiotherapy services will be developed over time to ensure that:

- **Safety:** Radiotherapy is delivered according to national standards
- **Uptake:** 52% of all cancer patients should be offered radiotherapy at some point in their pathway.
- **Access:** Local calculations based on Malthus predictions should be used to increase the number of attendances per million population by 2016. Up to 47,000 attendances per million population.
- **Access:** Earlier access to radiotherapy should be demonstrated by greater use of radical (rather than palliative) radiotherapy
- **Capacity:** An additional 13% capacity is identified as available to meet fluctuations in demand and technical development requirements. This is essential to be able to meet waiting times targets.
- **Wait for First Treatment:** Radiotherapy: 62 day from urgent referral to treatment and 31-Day Wait from decision to treat to treatment for all cancers and second or subsequent treatment: It is also expected that departments meet the Joint Collegiate Council for Oncology (JCCO) standards for radiotherapy treatment which should be regularly monitored by each service

department and shortcomings addressed.

- **Technology:** Inverse planned intensity Modulated Radiotherapy (IMRT) uptake: Inverse planned IMRT should be standard for a minimum of 24 % of all radical attendances. Image Guided Radiotherapy (IGRT) uptake: increase the number of patients receiving radical IMRT (Excluding brain and breast) with level 2 imaging.

The appropriate delivery of radiotherapy treatments to patients with cancer will ensure that the outcomes from treatment will meet the requirements of the 5 domains of the NHS Outcomes Framework

This specification forms schedule 2 part 1, The Services – Service Specifications of the Standard NHS contract for Acute services.

This specification has been developed to ensure that the services being delivered offer high quality external beam radiotherapy to patients by ensuring that:

- Accurate treatment is delivered in the context of a safety-conscious culture.
- Treatment is delivered within an evidence based approach and according to locally agreed protocols.
- Strong clinical and operational governance arrangements exist
- All patients with cancer who require radiotherapy (including urgent and palliative radiotherapy) as part of their treatment receive this in a timely manner.
- There is access to modern radiotherapy techniques, e.g. Intensity Modulated Radiotherapy (IMRT) and Image Guided Radiotherapy (IGRT). Services not able to offer this will be expected to have plans in place to move to routine IGRT over the next 12 months.
- Appropriate verification systems are routinely used to ensure accuracy and correct alignment (e.g. imaging and in-vivo dosimetry)
- The radiotherapy capacity is adequate to meet the current demand, to improve cure rates, prevent and relieve symptoms, and improve patients' experience, whilst minimising any long-term side effects of treatment.
- Information included in the mandated national radiotherapy dataset (RTDS) must be collected and submitted according to national requirements.
- The department has robust mechanisms in place for monitoring treatment outcomes. See Appendix A
- The provider must participate in the national peer review programme for Radiotherapy and defined audits within Peer Review should be produced and acted upon.
- Where any radiotherapy is used concurrently with other treatments (such as brachytherapy or chemotherapy), it should be integrated appropriately and scheduled to meet patients needs.
- Radiotherapy is accessible to all patients with cancer who require it regardless of gender, age, ethnicity, disability, religion or belief, sexual orientation or any other non-medical characteristics.
- Clinical trials that patients are eligible for should be discussed with them

This is set out in 'A Commissioning Framework for External Beam Radiotherapy Services' available on the National Cancer Action Team website (<http://www.ncat.nhs.uk/our-work/ensuring-better-treatment/radiotherapy>). This framework should be used to inform the detail within this specification.

The delivery of appropriate levels of radiotherapy as well as the delivery of high quality treatment forms the key priority for action as identified within the Improving Outcomes: A Strategy for Cancer, and also the NHS Operating Framework 2011/12

It is expected that as a consequence of local and national awareness and earlier diagnosis initiatives the demand for radiotherapy will increase over time as it is expected that patients will present with their disease at an earlier stage. The planning of service capacity should therefore reflect this anticipated growth and providers of radiotherapy services should be involved in these discussions.

The planning assumptions for services should be based on the National Radiotherapy Advisory Group (NRAG) recommendations and include a 13% additional capacity assumption in order to meet the fluctuations in demand and to accommodate time for technical developments prior to their inclusion into routine practice.

Radiotherapy services tend to be based in larger acute hospitals providing Tertiary services although some services are provided through "satellite" units of these centres. Currently there are 50 radiotherapy services in England set out on 58 hospital sites.

There is a requirement for providers to work as part of a Network Radiotherapy Group, working in collaboration with commissioners, to develop longer term plans for the expansion of local radiotherapy services.

These plans should take account of the range of NRAG recommendations but should specifically consider the impact of travel times for radiotherapy on patients with cancer. NRAG recommends that travel times should be less than 45 minutes for the majority of patients as this is known to impact on access and uptake. The logistics of this and the local demand for radiotherapy will vary by geography as well as epidemiology, demographics and related factors

Radiotherapy is usually given as an external beam treatment (the most common form). Brachytherapy and other treatment modalities such as the new emerging techniques e.g. intra-operative radiotherapy and proton beam therapy (newer form of radiotherapy not widely available in England) are within external beam radiotherapy but outside the scope of this document.

Radiotherapy is usually delivered by Linear Accelerators (Linacs) capable of delivering a highly focused beam of radiation. These machines are housed in specially designed protective rooms known as bunkers

It is expected that Intensity Modulated Radiotherapy (IMRT) will be routinely offered to appropriate patients from April 2013 in line with the prime Ministers pledge. Where

this is not possible providers, in consultation with commissioners, should offer patients the opportunity to receive this type of treatment at an alternative provider

Improving the quality of radiotherapy (IMRT, IGRT etc) is linked to improving outcomes. Access to technologies such as Image Guided Radiotherapy (IGRT), which together with intensity modulated therapy forms the bases of 4-D Adaptive radiotherapy, should be the standard of care for many patients. Providers unable to deliver (IGRT) should have plans in place to make this available over the next 12 months.

It is expected that trusts providing radiotherapy meet (and continue to meet) the requirements below:

- 62 day and 31 day waiting time requirement to include all radiotherapy treatments.
- Service has plans in place to meet the increased capacity required to deliver the locally predicted attendances per million population by 2016. (locally adjusted via the Malthus planning tool or local validated modelling).
- The service should deliver efficient and productive use of all radiotherapy equipment.
- Where radiotherapy services are provided at weekends and bank holidays, a full service is available.
- The service should be able to identify 13% additional capacity to meet fluctuations in demand and technical development requirements.
- Minimum size of a department should be 2 treatment machines (unless robust plans are agreed with commissioners) and where possible the maximum number of machines should not exceed 8 machines unless these are already in place.
- The workforce should be designed around the 4-tier career progression model.
- The service should comply with a minimum of 70% of the National Peer Review measures or have plans in place to address any shortcomings. It is expected that any immediate risks or serious concerns identified in the process are addressed as a matter of urgency.
- The service must have an accredited quality assurance system in place.
- The service should contribute significantly to understanding the impact of new and changing treatments and regimens to play into the planning assumptions of the future

A review of IMRT has been undertaken by the National Radiotherapy Implementation Group (NRIG) and identified that as a minimum 24% of all radical attendances for radiotherapy should be delivered using inverse planned IMRT. It is expected that departments will collect local data on forward planned treatments to demonstrate achievement of this standard as set out below.

Tumour site	% of all RT fractions	% pts who benefit	% all fractions as IMRT	
			Forward Planned	Inverse Planned
Breast	30%	30%	9%	-
Prostate	16%	80%		13%
Gynaecological	5%	20%		1%
H + N	8%	80%		6%
CNS	3%	60%		2%
Other sites	10%	20%		2%
		<b>Total</b>	<b>9%</b>	<b>24%</b>
		<b>Grand Total</b>	<b>33%</b>	

The table is for information only as recent advice suggests the measure should be expressed as percentage of radical attendances and not fractions

## 2.2 Service description/care pathway

Radiotherapy is the safe use of controlled doses of ionising radiation to treat people who have cancer. The aim of Radiotherapy is to deliver as high a dose of radiation as possible to the cancerous tumour/s whilst sparing the surrounding normal tissues. Radiotherapy is often used on its own or as part of a treatment plan including surgery or chemotherapy, or both.

An indication for radiotherapy is defined as 'a clinical situation in which radiotherapy is recommended as the treatment of choice on the basis of evidence that including radiotherapy leads to superior clinical outcome compared to alternative treatments (including no treatment)' (Barton & Delaney 2003, Radiotherapy in Cancer Care: estimating optimal utilisation from a review of evidence based clinical guidelines).

The process of Radiotherapy is complex and involves understanding of the principles of medical physics, radiobiology, radiation safety, dosimetry, radiation treatment planning, simulation and interaction of radiation with other treatment modalities.

Radiotherapy is generally delivered by a machine called a Linear Accelerator or 'linac', (note this is a generic term for all megavoltage radiotherapy equipment) which is housed in a thick concrete 'bunker' or specially adapted room in order to protect staff, patients and the public from radiation.

Radiotherapy is a key component of both radical treatment, which aims to cure the patient and palliative treatment for symptom relief in patients who are in the advanced stages of their cancer. Radical treatment is typically delivered to patients every weekday, over a number of weeks, depending on the tumour site. Radiotherapy treatments are measured in attendances. Most patients are treated on an outpatient basis. Patients receiving palliative radiotherapy treatments require

significantly fewer attendances and may attend on single or multiple occasions.

Radiotherapy is part of an overall cancer management and treatment pathway. Decisions on the overall treatment plan should relate back to an MDT discussion and decision (may not be possible for patients requiring urgent radiotherapy)

When treating children the service will additionally follow the standards and criteria outlined in the Specification for Children's Services (included in this Specification)

Where applicable pregnant women requiring radiotherapy should have access to assessment and/ or management from highly specialised tertiary maternity care.

### **Service model**

The service model is set out in the "A Commissioning Framework for External Beam Radiotherapy Services" published on the National Cancer Action Team web site <http://www.ncat.nhs.uk/our-work/ensuring-better-treatment/radiotherapy> this includes pathway and service standards. The model pathway is reproduced at Appendix A.

A high quality external beam radiotherapy service should ensure that:

- Accurate treatment is delivered in the context of a safety-conscious culture (i.e. quality systems to define/control process, image guidance and In Vivo Dosimetry (IVD))
- All patients with cancer who require radiotherapy (including urgent and palliative radiotherapy) as part of their treatment receive this in a timely manner.
- Each service should make use of R-PORT or similar to determine local capacity planning to improve efficiency
- There is access to modern radiotherapy techniques, e.g. Intensity Modulated Radiotherapy (IMRT), Image-Guided Radiotherapy (IGRT) and IVD in non-IMRT treatments
- Efficient and effective treatment planning processes are in place
- Radiotherapy capacity is used most effectively to improve cure rates, prevent and relieve symptoms, and improve patients' experience by minimising any long-term side effects of treatment.
- During machine breakdowns patients in "category 1" must not have their treatment disrupted or delayed. See Appendix B
- Information on the outcomes of radiotherapy treatment is collected including contributing to the National Radiotherapy Dataset (RTDS).
- There is regular participation in the National Cancer Peer Review Programme for radiotherapy and as part of this process audits are produced, and any recommendations actioned.
- Radiotherapy treatment is integrated appropriately with other possible aspects of treatment such as brachytherapy or chemotherapy.
- Radiotherapy is accessible to all patients with cancer who require this treatment regardless of gender, age, ethnicity, disability, religion.

In addition:

- The delivery of accurate treatment is the responsibility of all staff and each department must develop a safety-conscious culture as demonstrated by reporting to national reporting and learning service (NRLS)
- Regular reviews should be conducted to ensure that protocols remain up to date, and that staffing levels and skills mix are appropriate for the numbers of patients treated and complexity of treatments delivered.
- Good multidisciplinary working with clear communication is essential and such a culture must be actively developed. Patients and staff should be encouraged to question and raise concerns to which the provider is required to respond.
- The fine details of checks and verification procedures and how they are performed are critical in ensuring that they are effective and have the greatest chance of detecting an error.
- Such checking procedures should be regularly reviewed to ensure they add value and to eliminate those that have become redundant
- Radiotherapy providers must have protocols in place for on- treatment verification imaging.
- Radiotherapy providers must have protocols in place for in vivo dosimetry and this must be in routine use at the beginning of treatment for most patients.
- When a clinically significant incident occurs, it is essential that the patient is informed and offered appropriate support. It is also important to offer support to the staff involved in such an incident.
- Each department must have a system for reporting and analysing errors. The lessons learnt should be fed back to the staff in multidisciplinary meetings. It is required that the radiotherapy pathway coding system set out in 'Towards Safer Radiotherapy' is used to aid the sharing of information and learning between centres through the NRLS.
- Commissioners should be informed of clinically significant errors reported to patients as reported under the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) regulations.

It is imperative that the radiotherapy service is compliant with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000. These regulations (which now also include the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006) are legislation intended to protect the patient from the hazards associated with ionising radiation. Major errors within radiotherapy are reported under IR(ME)R and investigations are conducted under criminal law and under the threat of caution.

IR(ME)R is flexible and allows for a wide variety of practices to be undertaken as long as they are clearly justified. It is imperative that roles and responsibilities are clearly set out in procedures and that everyone understands their individual roles. Responsibility for compliance with IR(ME)R rests with the employer and all entitled duty holders as defined in the regulations.

The employer should be considered to be the chief executive unless an alternative individual has been formally designated as the employer. Under IR(ME)R, the

employer is legally responsible, when establishing practices for the safe delivery of radiotherapy, for ensuring that robust procedures exist including those listed in Schedule 1, (Regulation (4(1))). It is usual for the detailed implementation of IR(ME)R to be delegated to an appropriate professional. Providers need to demonstrate compliance with IR(ME)R and show clear lines of authority from the professional leads to the employer as the employer's responsibility cannot be delegated under IR(ME)R.

### **Referral processes and sources**

The radiotherapy service forms part of the pathway of cancer care for patients and it has been developed with formal links to the relevant multi-disciplinary teams in mind. The pathways must be reviewed formally on a regular basis and also adhere to the local network guidelines. User and carer involvement is an important step in this process.

Any NHS radiotherapy activity sub-contracted to another provider (eg satellite departments) or delivered by an external contractor should provide radiotherapy as part of the whole pathway. There must be clear and formal accountability processes and structures in place to ensure integration of clinical care that is safe and effective. All work processes should be protocol led and clearly defined both within the provider and with any other service provider particularly where the medical care could be from a number of different host providers. Any deviation from these protocols must be clearly documented and investigated with regular reviews, and where appropriate updated.

The majority of patients on a radiotherapy pathway should be discussed at an appropriate MDT

Referrals for radiotherapy are made to a Consultant Clinical Oncologist or other certified practitioner (such as a registered and appropriately trained consultant radiographer working under protocol), who is a member of that MDT. In some circumstances onward referral to another provider may be appropriate

It is essential that an individual consultant retains the responsibility for overall patient care across the whole pathway and will provide care when a patient is using a separate discrete radiotherapy service, and retains overall responsibility for the management of side effects and complications. A consultant practitioner (such as an appropriately trained and identified registered Therapeutic Radiographer working at Consultant level) may provide the link between the radiotherapy service and the multi-disciplinary team.

The service itself will also have clinical oversight and accountability for governance purposes. There must be a professional head of the radiotherapy service directly responsible for the development, management and ultimate clinical accountability and responsibility for the service. This professional head of service must hold an appropriate qualification to practise and be registered with the health professions council.

## **Patient Pathways**

At entry to the pathway, the provider must have systems and processes in place to

- register patients
- collect relevant clinical and administrative data
- manage the appointment process, (reappointment and Did Not Attend (DNA) process if appropriate).
- provide an appropriate range of information to patients which supports informed consent
- undertake initial assessment in the appropriate location

At point of intervention, the provider must have systems and processes in place to ensure that:

- the intervention is conducted safely and in accordance with accepted quality standards and good clinical practice.
- the patient receives appropriate care during the intervention(s), including on treatment review and support, in accordance with best clinical practice
- where clinical emergencies or complications do occur they are managed in accordance with best clinical practice
- the intervention is carried out in a facility which provides a safe environment of care and minimises risks to patients, staff and visitors
- the intervention is undertaken by staff with the necessary qualifications, skills, experience and competence
- There are arrangements for the management of out of hours care according to best clinical practice and monitored via a local recording system.

At exit from pathway, the provider must have systems and processes in place, which are agreed with all parties and networks to:

- undertake telephone triage
- make urgent onward referrals where life-threatening conditions or serious unexpected events occur during an intervention/assessment
- ensure that patients receive discharge information relevant to their intervention including arrangements for contacting the provider and follow up if required
- provide timely feedback to the referrer re intervention, complications and proposed follow up
- ensure that the patient receives required drugs/dressings/aids
- ensure that support is in place with other care agencies including the voluntary sector.
- Provide General Practitioners (GPs) and patients with treatment summaries monitored through a local recording system.

An example pathway for radiotherapy referral and pre-treatment planning is set out at Appendix A.

## **Treatment and post treatment care**

Radiotherapy is normally provided on an outpatient (OP) basis but patients may be

admitted due to their overall condition, concurrent chemotherapy or co- morbidities rather than as a result of their radiotherapy.

During and after treatment; patient contact with the wider cancer MDT (Clinical Nurse Specialist (CNS), Dietician etc.) should be maintained and encouraged. Supporting patients during and after radiotherapy is essential. Regular review of patients on a daily basis is the responsibility of the registered radiographer treating the patient, additionally regular formal review will involve a team approach that requires multiple skills and attention.

After treatment, patients will be given appropriate after treatment care and follow-up.

Patients should be given contact details of the service to support post treatment reactions and anxieties.

Following radiotherapy; the responsible clinician should confirm to both the patients GP and referring clinician what treatment has been delivered, the patient's condition and any post treatment arrangements.

### **Service user/ carer information**

For patients receiving radiotherapy, there should be written information, supplementary to that on any general consent form, which includes at least the following:

- patient-related aspects of radiotherapy treatment in general;
- patient-related aspects of treatment, both acute and late effects, specific to the anatomical sites treated and modalities used in the department.

The patient consent form for a course of radiotherapy treatment should be designed so that the person giving consent acknowledges that they have been offered the general and site-specific patient information. The treatment site should be specified on the consent form. Access to support and information out of hours by telephone should be available.

Additionally, every effort should be made to offer a patient their preferred treatment time, not to rearrange or cancel appointments unnecessarily and to limit the time patients have to wait for their appointment.

### **Service Development Strategy**

A service development strategy should be agreed with commissioners and be regularly reviewed. It should include an equipment replacement programme, a planned refresh of software, the introduction of new treatment techniques and services (e.g. IMRT new sites, IGRT roll out, SBRT, etc). The service development strategy should be informed by the heads of the 3 professional disciplines (Oncologist, Physicist, Radiographer) working in close partnership. The strategy as a minimum should focus on the implementation of IMRT and IGRT into routine clinical practice in line with table 5 and soon to be published NRIC guidance.

Additional evidence and guidance to support this is expected.

### **Equipment Replacement**

Radiotherapy equipment should be replaced regularly and trusts must ensure that all machines are listed as part of a capital replacement programme. NRAG recommends that all Linear Accelerators are replaced every 10 years and the computer software is updated every 3 years. Replacement of Computerised Tomography (CT) simulators is recommended within 10 years and associated planning equipment should be regularly upgraded

Equipment should be procured / provided to the standards as detailed in the national technical specification. This should specify an equipment maintenance schedule programme clarifying the use of in-house or external engineers. The equipment should be at least sufficient to meet the clinical requirements of the activity commissioned.

The provider should ensure that each Linear Accelerator is in operation for a maximum of 10 years and that the replacements are planned in a timely manner. Commissioners may divert activity where this is breached without agreement.

Oncology management systems should be utilised fully to enable streamlined patient and task scheduling across the radiotherapy pathway

### **Travel Times and access**

Patients are required to attend for radiotherapy on multiple visits up to 40 times over an 8 week period. The impact on patients should not be underestimated in this. Providers should be encouraged to minimise the impact of this through car parking concessions; dedicated parking spaces and well managed appointment processes. The impact on patients and their carers cannot be underestimated here. The provider should ensure that appropriate scheduling tools are used to ensure patient choice and improved access to services, and to maximize efficiency.

Radiotherapy is provided during day time hours usually on week days. Patients will however experience side effects on a 24 hour basis. Providers should be encouraged to demonstrate how patients will be supported when the radiotherapy facility is closed.

### **Service Operating Schedule**

The service will be available for at least 239 days per year, as recommended by NRAG, including 5 of the 8 bank holidays. The working day for at least one of the linear accelerators should be in line with NRAG recommendations proportionate to the numbers of patients. National and local patient information should be used to determine uptake of services at weekends and extended hours. Where sufficient patients show a preference for extended weekend or evening working; the service will comply with this. Appropriate support services must be available to patients to

ensure equitable services for patients attending outside the “normal” working hours

The provider should have in place contingency plans and arrangements for the management of patients during periods of staff shortage and machine maintenance and breakdown (see Guidelines for the Management of the Unscheduled Interruption or Prolongation of a Radical Course of Radiotherapy). Category 1 patients are defined at Appendix B.

Cover arrangements for absence and holidays, out of hours and emergencies must be in place to ensure continuity of service, and may include links with the main radiotherapy centre for shared rotas as appropriate.

### **Productivity**

Providers should use the nationally developed ‘Productive Radiotherapy Service’ template to assess productivity and the outcomes from this used to inform productivity discussions with commissioners of the service. This should include the use of R-PORT (or similar) as a local capacity modelling tool.

### **Workforce**

Multidisciplinary workforce planning for the service should be undertaken with input from the radiographer, physics and oncologist leads. The Workforce Integrated Planning Tool (WipT) should be utilised to model future staffing requirements using the Malthus feed.

This is essential to ensure that the most appropriate staffing and skills mix is agreed, and the service should ensure that the workforce profiles are guided by the professional body staffing recommendations. The 4 tier structure (career progression framework) should be used to ensure therapeutic radiographers skills are utilised effectively and efficiently for the therapeutic radiographer radiographic workforce. “Implementing the career framework in radiotherapy - policy into practice”  
<http://doc-lib.sor.org/implementing-career-framework-radiotherapy-policy-practice>

The provider should ensure that the workforce (i.e. radiographers, medical physicists, oncologists, clinical technologists, dosimetrists and other support and administrative staff) has the appropriate minimum levels of experience, qualifications, staff development and competencies as outlined in the contracting framework for external beam radiotherapy services and registered with the regulatory body. For example: The appropriate skill mix of senior and junior radiographers, advanced practitioner radiographers, consultant practitioner radiographers and supporting staff such as assistant practitioners, for each treatment and planning processes,.

Evidence of continuing professional development and training records (to support the implementation of new techniques and technologies) that is up to date should be available.

Workforce planning (forecasting future activity and treatment technology) should be

regularly undertaken ensuring the most appropriate workforce and skills mix (using WipT) is available to support the radiotherapy treatment pathways.

### **Satellite and additional capacity models**

Where additional capacity models are operated off the main radiotherapy site (eg satellite radiotherapy or alternative provider); clear governance arrangements and operating models should be in place and should include:

- The service, if operating a satellite service type model, will be required to set up and maintain formal links with a designated Cancer Centre and radiotherapy department which should include governance arrangements, staff training and development, the use and role of networked technology, and clinical cross- cover arrangements.
- The service should be set up to support compliance with the NICE Improving Outcomes Guidance for all cancer services, and fulfil / participate in membership of the relevant multi-disciplinary teams as required.
- There must be protocols in place for handover of responsibility between clinicians to ensure smooth transition in support for patients throughout the cancer pathway; protocols must be network wide and easily accessible to all healthcare staff involved in the delivery of Radiotherapy
- Radiotherapy staff will be expected to meet the requirement for attendance at MDTs.
- Subcontracting arrangements should not be entered into without the agreement of the commissioners. There should be clear and formal agreements between the provider and any sub-contractor in the form of a service level agreement, detailing the part played by the sub-contractor in the radiotherapy service, and the arrangements for clinical accountability and responsibility between the two parties.
- All work processes should be protocol led and clearly defined both within the provider and with any other service provider. Any deviation from these protocols will be clearly documented and investigated with regular reviews and where appropriate updated. Any satellite unit must demonstrate compliance with the clinical governance and leadership arrangements of the main provider organisation. Protocols should at least be in harmony with those of the tertiary organisation and ratified by the relevant Network Radiotherapy Group.

### **2.3 Population covered**

The service outlined in this specification is for patients ordinarily resident in England and includes radiotherapy treatments delivered to both adult and Paediatric patients for whom radiotherapy has been deemed an appropriate treatment and who have agreed to receive this treatment. Typically, patients requiring radiotherapy will have been discussed at least once at an MDT.

Services for children are concentrated in 21 specialist centres across the UK.

Radiotherapy must be provided by specialist clinical oncologists in a child friendly environment with specialist support staff including play therapy.

Radiotherapy should be accessible to all patients with cancer who require this treatment regardless of gender, age, ethnicity, disability, religion or belief, sexual orientation or any other non-medical characteristics

## **2.4 Any acceptance and exclusion criteria**

### **Acceptance Criteria**

Access to radiotherapy is recognised to be below that in many other countries (37% versus 52% of all diagnosed cancer patients). This is believed to relate (in part) to late presentation and stage at diagnosis. Commissioners and providers should be working together to influence referral patterns and earlier diagnosis to improve the uptake of and the outcomes from radiotherapy.

The service must comply with current legislation and local and national policies and standards in relation to Equality and Diversity. The Provider will ensure that the service offered is respectful and must not discriminate on grounds of age, gender, sexuality, ethnicity or religion. The service should be sensitive to the needs of people whose first language is not English and those with hearing, visual or learning disabilities.

The provider will facilitate compliance with the Disability Discrimination Act (2005) by ensuring that all reasonable adjustments are made to remove the barriers to access by disabled people.

The provider will comply with Equalities legislation including the Race Relations (Amendment) Act 2000 and Equalities Act 2006 and aim to meet the individual needs of the service users irrespective of race, disability, gender, religion/belief, age and sexual orientation

The provider has a duty to include people with learning difficulties in its activities, and should recognise they may need more support and preparation in order to access services.

Information supplied about the service must be sensitive, clear and professional and in formats appropriate to the needs of users and potential users of the service.

The provider should consider accessibility and acceptability of the facilities available for the service, such as ease of access, privacy, comfort and include these issues in audits of patient satisfaction.

### **Any exclusion criteria**

This specification does not cover the use of Brachytherapy, molecular radiotherapy unused (Radio pharmaceutical), protons, intra-operative radiotherapy

and treatments using unsealed and sealed radioactive sources. These treatments are subject to some additional requirements to the principles identified within this specification.

## **2.5 Interdependencies with other services**

Some patients will receive radiotherapy as a pre or post-surgical plan. Some patients will receive chemotherapy and or hormone therapy in conjunction with their radiotherapy

Critically, radiotherapy services should have access to a range of support services, including diagnostic services and patients should have access to the extended support teams (e.g. occupational therapy and physiotherapy), particularly for the management of late effects which should be co-located and accessible to meet the needs of patients.

Radiotherapy services are often but not exclusively co-located with chemotherapy services. Where services are not co-located but form part of multimodality treatment appropriate governance must be in place around transfer of information, access to emergency care.

All patients requiring radiotherapy should have access to appropriate other health professionals including a Dietician, Speech and Language Therapist, their Clinical Nurse Specialist, Pathology, Radiology and similar support services.

Co-ordinated approaches to the planning of radiotherapy should be undertaken as part of a cancer network. The service should be part of at least one cancer network and there should be significant representation from the local service on the Network Radiotherapy Group.

The service should work closely with its local, regional and national colleagues to ensure continuous quality improvement.

## **3. Applicable Service Standards**

### **3.1 Applicable national standards e.g. NICE, Royal College**

The following standards and principles are core standards:

“Joint Council for Clinical Oncology (1993) Reducing Delays in Cancer Treatment: Some Targets. London: Royal College of Physicians”

The Royal College of Radiologists (RCR) sets out clear guidance on waits for radiotherapy that goes beyond the mandatory cancer waits. These reflect good practice guidance and should be the standard of care where possible

They set out:

- No patients waiting longer than 28 days for radical treatment
- No patients waiting longer than 14 days for palliative treatment
- No patients waiting longer than 48 hours for urgent treatment

The RCR also sets out guidance for interruptions to treatment; and the cases where this can have a serious deleterious effect on outcome with decreased cure rates. In this, the RCR sets out that category one patients (those with rapidly growing tumours such as Squamous cell tumours) should not have unscheduled breaks in treatment and where these are unavoidable; they should be compensated for.

### **3.2 Quality Standards and Governance**

The service will comply with the relevant and current quality standards. This are defined in 'A Commissioning Framework for External Beam Radiotherapy Services' available on the National Cancer Action Team website <http://www.ncat.nhs.uk/our-work/ensuring-better-treatment/radiotherapy>

The service will have a quality system registered and accredited to the appropriate quality standard.

Within this the service will have detailed clinical protocols setting out nationally recognised good practice for each treatment site.

The Quality System and its treatment protocols will be subject to regular clinical and management audit.

The Quality System will be externally accredited by an appropriate body.

The service will comply with the National Cancer Peer Review process and endeavour to meet all appropriate standards, with a minimum 70% compliance. Where this is not possible the service will develop and implement an agreed action plan.

Clinical Governance systems and policies should be in place and integrated into organisational governance with clear lines of accountability and responsibility for all clinical governance functions and Providers should produce annual Clinical Governance reports as part of NHS Clinical Governance reporting system

The provider is required to undertake annual patient surveys and develop and implement an action plan based on the findings.

The provider must be able to offer patient choice. This will be both in the context of appointment time and of treatment options including treatments not available locally.

## Principles

The service specification is based on the following principles:

- All satellite / alternative provider units delivering radiotherapy for the NHS should have formal and defined linkages to a cancer centre.
- All new patients receiving radiotherapy should have been discussed by an appropriate cancer centre or cancer unit multi-disciplinary team before being accepted for treatment.
- All patient treatment plans must be supervised by a multi-disciplinary team member with the appropriate competencies.
- All staff within the Service should have active participation in the working groups of their network(s) and be involved in the development of network policies and guidance and should work in accordance with them.
- All new clinical developments should be assessed prior to their introduction to ensure that they fit with strategic plans developed by commissioners and networks.
- There must be a robust system of clinical governance in place and all staff must be fully familiar with the treatment techniques employed within the service and be trained and deemed competent to deliver them.
- Service improvement should be shaped by service user and carer involvement.
- Equity of access and quality of care should be provided to all who need it regardless of sex, age, gender or ethnicity unless there is robust evidence that these factors affect the effectiveness of the intervention/treatment.
- Clinical trials that patients are eligible for should be discussed with them.
- Active promotion of education and self-management for people with cancer and other conditions should be undertaken at every opportunity.
- The service should be actively working towards providing personalised care for patients, with service flexibility to match the individual's needs.
- Patients should receive the right treatment, at the right time, in the right place, which, where possible, will be as close to home as practicable.
- Patients must receive clear written guidance when consenting to treatment to include the treatment intent, prognosis and potential complications associated with their treatment with clear instructions who to contact if they need advice outside working hours and how to proceed in the event of a medical emergency.
- The service should be able to demonstrate effective clinical leadership and decision making
- The service should be well integrated with the rest of the cancer service and be able to demonstrate effective participation in multi-disciplinary team meetings to ensure well managed transitions between services and across primary, secondary and tertiary care boundaries.
- The service should employ models of care, interventions and treatments that are evidence based.
- The service should demonstrate full exploitation of the existing equipment, workforce knowledge and skills including the development of new roles for all health professionals, where appropriate.
- Care pathways should be managed using proactive case management models.
- The service should use technology, audit, data management and analysis, service reviews, intelligence and other techniques to evaluate its effectiveness

and to drive continuous service improvement

#### 4. Key Service Outcomes

Performance indicator	Indicator	Threshold	Method of Measurement	Consequence of Breach
Waits: First Definitive Treatment	% patients waiting less than or equal to 62 days	85%	Cancer waiting time- database (CWT-db)	National requirement breached
Waits: Subsequent Treatment	% patients waiting less than or equal to 31 days	94%	CWT-db	National requirement breached
Radical Radiotherapy	% uptake of radical radiotherapy	>50% of episodes should be radical >83% of attendances should be radical	Radiotherapy dataset (RTDS)	
IMRT	% of radical attendances delivered using Inverse planned IMRT	24% of radical attendances	RTDS	
IGRT	% patients receiving treatment with image guided radiotherapy		RTDS	
Uptake	% of all diagnosed cancer patients being offered radiotherapy during their cancer pathway	52%	RTDS and National cancer data repository (NCDR)	

Access	Number of Attendances per million population	Locally modelled through Malthus	RTDS	
Quality compliance with national Peer Review	% compliance plus number of immediate risks or serious concerns		CQUINS	Governance issue
Patient Experience	Number of patients reporting positively through cancer patient experience survey	83%	Cancer Patient Experience Survey (CPES) via Cancer commissioning toolkit	
Patient satisfaction of radiotherapy service	% of patients reporting satisfaction with the radiotherapy service as defined by the 10 measures under development	Greater than the preceding year annual median	Cancer Commissioning toolkit National Patient Survey	
Unscheduled delays to treatment	All patients in category 1 must not have their treatment delayed or interrupted	95% of the group treated	Audit	
Equipment age profile	Age of linear accelerators	Number of Linacs in each year of age (maximum expected age is 10 years)	Cancer Commissioning Toolkit	
Exposure profile	Efficient use of Linear Accelerators	Number of exposures per small time increment	Cancer Commissioning Toolkit	

Metrics are being developed to determine:

- The number of patients completing their course of treatment as prescribed
- The overall length of the radiotherapy pathway (rather than the 31 day requirement)
- Fractionation profile against national good practice
- Workforce profile 30 and 90 day mortality equivalents

## **Additional standards for the provision of services to children**

### **Aims and objectives of service**

**This specification to annexe applies to all children's services and outlines generic standards and outcomes that would be fundamental to all services**

The generic aspects of care:

The Care of Children in Hospital (HSC 1998/238) requires that:

- Children are admitted to hospital only if the care they require cannot be as well provided at home, in a day clinic or on a day basis in hospital.
- Children requiring admission to hospital are provided with a high standard of medical, nursing and therapeutic care to facilitate speedy recovery and minimise complications and mortality.
- Families with children have easy access to hospital facilities for children without needing to travel significantly further than to other similar amenities
- Children are discharged from hospital as soon as socially and clinically appropriate and full support provided for subsequent home or day care.
- Good child health care is shared with parents/carers and they are closely involved in the care of their children at all times unless, exceptionally, this is not in the best interest of the child; accommodation is provided for them to remain with their children overnight if they so wish.

### **Service description/care pathway**

All paediatric specialised services have a component of primary, secondary, tertiary and even quaternary elements.

The efficient and effective delivery of services requires children to receive their care as close to home as possible dependent on the phase of their disease.

Services should therefore be organised and delivered through "integrated pathways of care" (*National Service Framework for children, young people and maternity services*, Department of Health & Department for Education and Skills, London, 2004)

## **Interdependencies with other services**

All services will comply with 'Commissioning Safe and Sustainable Specialised Paediatric Services: A Framework of Critical Interdependencies' – Department of Health

### **Imaging**

All services will be supported by a three-tier imaging network ('Delivering quality imaging services for children', Department of Health 13732 March, 2010). Within the network:

- It will be clearly defined which imaging test or interventional procedure can be performed and reported at each site
- robust procedures will be in place for image transfer for review by a specialist radiologist, these will be supported by appropriate contractual and information governance arrangements
- robust arrangements will be in place for patient transfer if more complex imaging or intervention is required
- common standards, protocols and governance procedures will exist throughout
- all radiologists, and radiographers will have appropriate training, supervision and access to continuing professional development
- all equipment will be optimised for paediatric use and use specific paediatric software

### **Specialist Paediatric Anaesthesia**

Wherever and whenever children undergo anaesthesia and surgery, their particular needs must be recognised and they should be managed in separate facilities, and looked after by staff with appropriate experience and training.<sup>1</sup> All UK anaesthetists undergo training which provides them with the competencies to care for older babies and children with relatively straightforward surgical conditions and without major co-morbidity. However those working in specialist centres must have undergone additional (specialist) training<sup>2</sup> and should maintain the competencies so acquired<sup>3</sup> \*. These competencies include the care of very young/premature babies, the care of babies and children undergoing complex surgery and/or those with major/complex co-morbidity (including those already requiring intensive care support).

As well as providing an essential co-dependent service for surgery, specialist anaesthesia and sedation services may be required to facilitate radiological procedures and interventions (for example Magnetic Resonance Imaging (MRI) scans and percutaneous nephrostomy) and medical interventions (for example joint injection and intrathecal chemotherapy), and for assistance with vascular access in babies and children with complex needs such as intravenous feeding.

Specialist acute pain services for babies and children are organised within existing departments of paediatric anaesthesia and include the provision of agreed (hospital

wide) guidance for acute pain, the safe administration of complex analgesia regimes including epidural analgesia, and the daily input of specialist anaesthetists and acute pain nurses with expertise in paediatrics

\*The Safe and Sustainable reviews of paediatric cardiac and neurosciences in England have noted the need for additional training and maintenance of competencies by specialist anaesthetists in both fields of practice.

## References

1. Guidelines Paediatric Anaesthetic Services Paediatric anaesthetic services (GPAS). RCoA 2010 [www.rcoa.ac.uk](http://www.rcoa.ac.uk)
2. Certificate of Completion of Training (CCT) in Anaesthesia 2010
3. Continuing Professional Development (CPD) matrix level 3

## Specialised Child and Adolescent Mental Health Services (CAMHS)

The age profile of children and young people admitted to specialised CAMHS day/in-patient settings is different to the age profile for paediatric units in that it is predominantly adolescents who are admitted to specialised CAMHS in-patient settings, including over-16s. The average length of stay is longer for admissions to mental health units. Children and young people in specialised CAMHS day/in-patient settings generally participate in a structured programme of education and therapeutic activities during their admission.

Taking account of the differences in patient profiles the principles and standards set out in this specification apply with modifications to the recommendations regarding the following

- Facilities and environment – essential Quality Network for In-patient CAMHS (QNIC) standards should apply  
<http://www.rcpsych.ac.uk/quality/quality accreditation/audit/qnic1.aspx>
- Staffing profiles and training - essential QNIC standards should apply.
- The child/ young person's family are allowed to visit at any time of day taking account of the child / young person's need to participate in therapeutic activities and education as well as any safeguarding concerns.
- Children and young people are offered appropriate education from the point of admission.
- Parents/carers are involved in the child/young person's care except where this is not in the best interests of the child / young person and in the case of young people who have the capacity to make their own decisions is subject to their consent.
- Parents/carers who wish to stay overnight are provided with accessible accommodation unless there are safeguarding concerns or this is not in the best interests of the child/ young person.

## **Applicable national standards e.g. NICE, Royal College**

Children and young people must receive care, treatment and support by staff registered by the Nursing and Midwifery Council on the parts of their register that permit a nurse to work with children (Outcome 14h Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

- There must be at least two Registered Children's Nurses (RCNs) on duty 24 hours a day in all hospital children's departments and wards.
- There must be an Registered Children's Nurse available 24 hours a day to advise on the nursing of children in other departments (this post is included in the staff establishment of two RCNs in total).

Accommodation, facilities and staffing must be appropriate to the needs of children and separate from those provided for adults. All facilities for children and young people must comply with the Hospital Build Notes HBN 23 Hospital Accommodation for Children and Young People NHS Estates, The Stationary Office 2004.

All staff who work with children and young people must be appropriately trained to provide care, treatment and support for children, including Children's Workforce Development Council Induction standards (Outcome 14b Essential Standards of Quality and Safety, Care Quality Commission, London 2010).

Each hospital which admits inpatients must have appropriate medical cover at all times taking account of guidance from relevant expert or professional bodies (National Minimum Standards for Providers of Independent Healthcare, Department of Health, London 2002). "Facing the Future" Standards, Royal College of Paediatrics and Child Health.

Staff must carry out sufficient levels of activity to maintain their competence in caring for children and young people, including in relation to specific anaesthetic and surgical procedures for children, taking account of guidance from relevant expert or professional bodies (Outcome 14g Essential Standards of Quality and Safety, Care Quality Commission, London 2010).

Providers must have systems in place to gain and review consent from people who use services, and act on them (Outcome 2a Essential Standards of Quality and Safety, Care Quality Commission, London 2010). These must include specific arrangements for seeking valid consent from children while respecting their human rights and confidentiality and ensure that where the person using the service lacks capacity, best interest meetings are held with people who know and understand the person using the service. Staff should be able to show that they know how to take appropriate consent from children, young people and those with learning disabilities (Outcome 2b) (Seeking Consent: working with children Department of Health, London 2001).

Children and young people must only receive a service from a provider who takes steps to prevent abuse and does not tolerate any abusive practice should it occur. Outcome 7 Essential Standards of Quality and Safety, Care Quality Commission, London 2010, defines the standards and evidence required from providers in this

regard). Providers minimise the risk and likelihood of abuse occurring by:

- ensuring that staff and people who use services understand the aspects of the safeguarding processes that are relevant to them.
- ensuring that staff understand the signs of abuse and raise this with the right person when those signs are noticed.
- ensuring that people who use services are aware of how to raise concerns of abuse.
- having effective means to monitor and review incidents, concerns and complaints that have the potential to become an abuse or safeguarding concern.
- having effective means of receiving and acting upon feedback from people who use services and any other person.
- taking action immediately to ensure that any abuse identified is stopped and suspected abuse is addressed by:
  - having clear procedures followed in practice, monitored and reviewed that take account of relevant legislation and guidance for the management of alleged abuse
  - separating the alleged abuser from the person who uses services and others who may be at risk or managing the risk by removing the opportunity for abuse to occur, where this is within the control of the provider
  - reporting the alleged abuse to the appropriate authority
  - reviewing the person's plan of care to ensure that they are properly supported following the alleged abuse incident
- using information from safeguarding concerns to identify non-compliance, or any risk of non-compliance, with the regulations and to decide what will be done to return to compliance.
- working collaboratively with other services, teams, individuals and agencies in relation to all safeguarding matters and has safeguarding policies that link with local authority policies.
- participating in local safeguarding children boards where required and understand their responsibilities and the responsibilities of others in line with the Children Act 2004.
- having clear procedures followed in practice, monitored and reviewed in place about the use of restraint and safeguarding.
- taking into account relevant guidance set out in the Care Quality Commission's Schedule of Applicable Publications
- ensuring that those working with children must wait for a full CRB disclosure before starting work.
- training and supervising staff in safeguarding to ensure they can demonstrate the competences listed in Outcome 7E of the Essential Standards of Quality and Safety, Care Quality Commission, London 2010

All children and young people who use services must be:

- fully informed of their care, treatment and support.
- able to take part in decision-making to the fullest extent that is possible.
- asked if they agree for their parents or guardians to be involved in decisions they need to make.

(Outcome 4I, Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

### Key Service Outcomes

Evidence is increasing that implementation of the national *Quality Criteria for Young People Friendly Services* (Department of Health, London 2011) have the potential to greatly improve patient experience, leading to better health outcomes for young people and increasing socially responsible life-long use of the NHS. Implementation is also expected to contribute to improvements in health inequalities and public health outcomes e.g. reduced teenage pregnancy and Sexually Transmitted infections (STI), and increased smoking cessation. All providers delivering services to young people should be implementing the good practice guidance which delivers compliance with the quality criteria.

Poorly planned transition from young people's to adult-oriented health services can be associated with increased risk of non-adherence to treatment and loss to follow-up, which can have serious consequences. There are measurable adverse consequences in terms of morbidity and mortality as well as in social and educational outcomes. When children and young people who use paediatric services are moving to access adult services (for example, during transition for those with long term conditions), these should be organised so that:

- all those involved in the care, treatment and support cooperate with the planning and provision to ensure that the services provided continue to be appropriate to the age and needs of the person who uses services.

The *National Minimum Standards for Providers of Independent Healthcare*, (Department of Health, London 2002) require the following standards:

- **A16.1** Children are seen in a separate out-patient area, or where the hospital does not have a separate outpatient area for children, they are seen promptly.
- **A16.3** Toys and/or books suitable to the child's age are provided.
- **A16.8** There are segregated areas for the reception of children and adolescents into theatre and for recovery, to screen the children and adolescents from adult patients; the segregated areas contain all necessary equipment for the care of children.
- **A16.9** A parent is to be actively encouraged to stay at all times, with accommodation made available for the adult in the child's room or close by.
- **A16.10** The child's family is allowed to visit him/her at any time of the day, except where safeguarding procedures do not allow this
- **A16.13** When a child is in hospital for more than five days, play is managed and supervised by a qualified hospital play specialist.
- **A16.14** Children are required to receive education when in hospital for more than five days; the Local Education Authority has an obligation to meet this need and are contacted if necessary.
- **A18.10** There are written procedures for the assessment of pain in children and the provision of appropriate control.

All hospital settings should meet the *Standards for the Care of Critically Ill Children* (Paediatric Intensive Care Society, London 2010).

There should be age-specific arrangements for meeting Regulation 14 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. These require:

- a choice of suitable and nutritious food and hydration, in sufficient quantities to meet service users' needs
- food and hydration that meet any reasonable requirements arising from a service user's religious or cultural background
- support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs.
- for the purposes of this regulation, "food and hydration" includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed.
- providers must have access to facilities for infant feeding, including facilities to support breastfeeding (Outcome 5E, of the *Essential Standards of Quality and Safety*, Care Quality Commission, London 2010)

All paediatric patients should have access to appropriately trained paediatric trained dieticians, physiotherapists, occupational therapists, speech and language therapy, psychology, social work and CAMHS services within nationally defined access standards.

All children and young people should have access to a professional who can undertake an assessment using the Common Assessment Framework and access support from social care, housing, education and other agencies as appropriate

All registered providers must ensure safe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines (Outcome 9 *Essential Standards of Quality and Safety*, Care Quality Commission, London 2010). For children, these should include specific arrangements that:

- ensure the medicines given are appropriate and person-centred by taking account of their age, weight and any learning disability
- ensure that staff handling medicines have the competency and skills needed for children and young people's medicines management
- ensure that wherever possible, age specific information is available for people about the medicines they are taking, including the risks, including information about the use of unlicensed medicine in paediatrics.

Many children with long term illnesses have a learning or physical disability.

Providers should ensure that:

- they are supported to have a health action plan
- facilities meet the appropriate requirements of the Disability Discrimination Act 1995
- they meet the standards set out in *Transition: getting it right for young people*.
- *Improving the transition of young people with long-term conditions from children's to adult health services*, Department of Health, 2006, London

<b>Service Specification No.</b>	<i>Cross reference External Beam Radiotherapy</i>
<b>Service</b>	Paediatric Radiotherapy
<b>Commissioner Lead</b>	
<b>Provider Lead</b>	
<b>Period</b>	12 months
<b>Date of Review</b>	

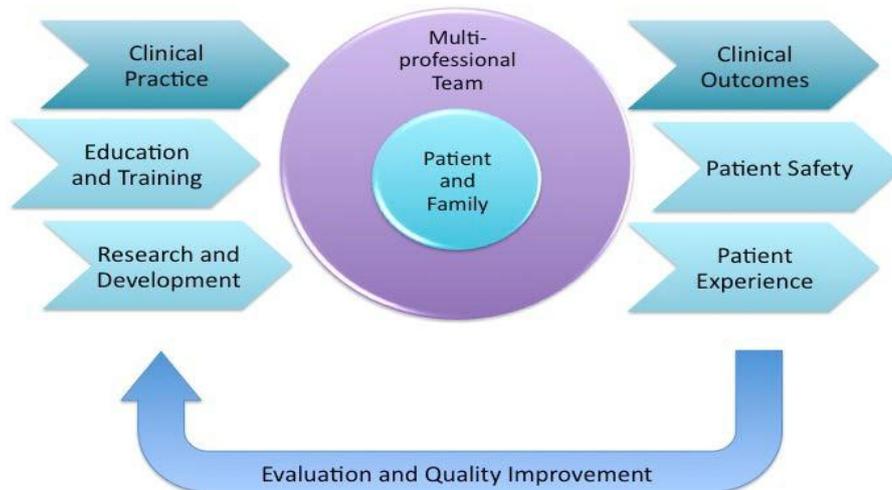
## 2. Scope

### 2.1 Aims and objectives of service

#### The care of children and teenagers with cancer

Cancer in children is rare. About 1,500 children under the age of 16 years develop cancer or leukaemia each year in the United Kingdom. They have a wide variety of diseases, each of which comes with a range of risk factors. These govern treatment and outcome, and when coupled with differing family circumstances mean that each child is unique. Patient care is complex and involves the input of many different healthcare professionals. It is coordinated by specialised multi-disciplinary teams at one of 19 principal treatment centres, and is often delivered in conjunction with staff at paediatric oncology shared care units closer to home and in the community. Rarely, the best type of radiotherapy for an individual patient may not be available at the closest paediatric radiotherapy centre, and referral to another city or even abroad may be required.

Radiotherapy is a component of treatment for many children with malignant disease. While this contributes to the likelihood of cure, it can also result in adverse effects. For best results, radiotherapy must be given by an experienced and well-trained team in a well-equipped department with appropriate specialist paediatric and adolescent support. The different needs of teenagers compared with younger children must be recognised. Excellent communication both between colleagues and with patients and their families is essential. Research to clarify the role and to improve the effectiveness of radiotherapy is also necessary.



As children's cancer is rare, paediatric clinical oncologists should develop professional networks through membership of organisations like the Children's Cancer and Leukaemia Group and the Paediatric Radiation Oncology Society and by attending meetings and conferences.

## 2.2 Service description/care pathway

**The pathway is described on page 34.**

For children and young people with cancer, Multidisciplinary team (MDT) working is an integral and essential part of modern cancer management. The primary function of an MDT is clinical to ensure that:

- All relevant information is available
- All the relevant treatment options are considered
- Options and decisions about patient care are documented [ref]

This is particularly important for the optimum management of paediatric tumours because of their rarity and complexity of multi-modality treatment. The structure of MDT working has been formalised by NICE through its Improving Outcomes Guidance for Children and Young People with Cancer.

Membership will include paediatric and clinical oncologists, surgeons, radiologists, pathologists, and other relevant healthcare professionals. There will be a core membership and an extended membership which brings other expertise as appropriate. Established staff should be facilitated to attend paediatric oncology and radiotherapy meetings and courses to maintain and improve their knowledge base and skills

It is essential that clinical oncologists with responsibility for paediatric radiotherapy are fully integrated core members of the paediatric oncology MDT to ensure that patients for whom radiotherapy may be appropriate are not overlooked. Therapy radiographers can also make a valuable contribution to these MDT meetings.

A documented discussion with a clinical oncologist of a patient at the MDT, although essential, is not of itself a referral. The discussion should be followed up with a formal written referral containing all relevant information to enable good communication and appropriate treatment in the light of the family circumstances

The planning, delivery and aftercare of radiotherapy for children and young people is a complex multi-professional activity. It requires clinical oncologists, therapy radiographers, mould room staff and play specialists supported by nurses, anaesthetic staff, physicists and dosimetrists, and psychologists or psychotherapists. The members of this team must have regular meetings to communicate about the requirements of individual patients.

### **2.3 Population covered**

Delivery of care to children has complexities which do not exist in adult practice, and so more time is often needed for consultation, preparation, planning and treatment. It is essential that all members of the team have training in, experience of, and continuing development in paediatric issues. 'Paediatric' practice ranges from babies and toddlers through primary school age children to younger teenagers. Patients should be treated in age appropriate ways in age appropriate facilities.

There should be integration of the therapeutic radiographer into the paediatric oncology multi-disciplinary team. The radiographer must have specific training and take the lead responsibility for children and young people.

All radiographers in a department treating children should receive Level 1 training for safeguarding children.

Children may or may not have the capacity to consent. This depends not just on age but more importantly on their level of development and understanding. At 16 years of age a young person can be presumed to have the capacity to consent. Under 16, a young person may have capacity, depending on their maturity and ability to understand what is involved. Children with capacity should be encouraged to involve their parents in decision making.

The family should be offered the opportunity to receive a written summary of the radiotherapy consultation. This should normally be a summary produced specifically for the family and appropriate resources in terms of time and secretarial support should be made available to enable copying of letters to patient's and or their families.

Immobilisation is a prerequisite for accurate radiotherapy. Most children older than three to four years of age can be encouraged to lie still with good radiotherapy play specialist input. Anaesthesia is required for younger children, and some older patients with learning difficulties or behavioural problems, and is more likely to be needed if beam-directing shells or prone positioning are used.

## 2.4 Interdependencies with other services

Safe paediatric anaesthesia, which is conducted in an area remote from the normal environment of anaesthetists with immediately available support in the event of a problem, requires an experienced team. This should be led by a consultant paediatric anaesthetist supported by an operating department practitioner and nurse. There should be a full range of paediatric anaesthetic and resuscitation equipment available.

A paediatric anaesthetic service should be available as often as necessary. This is at least five times a week on a regular basis, and a weekend service may occasionally be required for emergencies or to compensate for gaps caused by machine breakdown or public holidays. As some current treatment protocols call for hyperfractionated, accelerated treatment, a twice a day service may be needed on occasions.

The play specialist will make an initial assessment as to whether radiotherapy without the need for anaesthesia is possible. If it is, or if there is uncertainty, additional play sessions may be scheduled to help to prepare the child.

Excellent communication skills are essential for all oncologists, and all should have been on an advanced communication skills course. Paediatric clinical oncologists need to develop expertise in talking to children and young people in an age appropriate way, and also in communicating well with parents and other family members.

Patients and their families need to be seen regularly through treatment – usually at weekly intervals. This is the opportunity for monitoring of toxicity, and to answer questions which often arise after the initial consultations.

It is essential that children undergoing radiotherapy or chemo-radiotherapy have rapid access to expert paediatric supportive care to manage complications of their disease, toxicity of treatment and co-morbidity. This will often be the referring paediatric oncology team, or may be shared care paediatricians in local hospitals closer to that patient's home.

Common problems include myelosuppression with the need for blood product support, neutropenic sepsis, fluid and electrolyte disturbances if there is severe vomiting or diarrhea, and the need for neurosurgical investigation or intervention if obstructive hydrocephalus develops. Paediatric support is also needed in the radiotherapy department for resuscitation, and paediatricians should be immediately available during the administration of IV contrast in case of an adverse reaction.

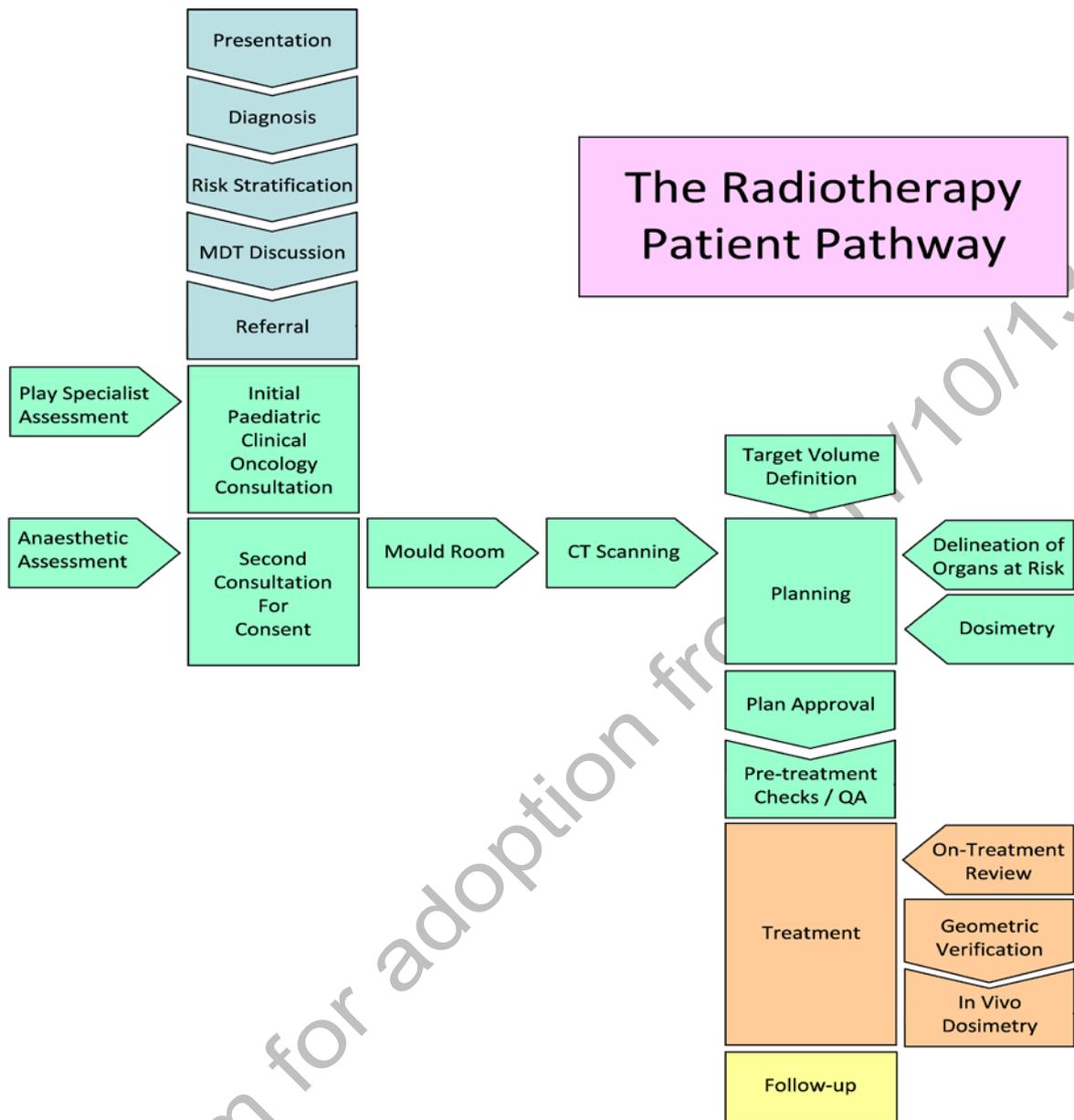
Not all late effects of cancer treatment are caused by radiotherapy – surgery and chemotherapy can also result in permanent functional or cosmetic impairment. Some late effects are more likely in some individuals because of a genetic predisposition. Late effects should be discussed in the wider context, not just in

relation to radiotherapy.

**Section amended from original – please see explanatory note**

*It was agreed by the Radiotherapy CRG in January 2014 that the key service outcomes included in the Paediatric section of this service specification should be removed as they had been included in error as the key service outcomes apply to the full cohort of patients receiving radiotherapy.*

Interim for adoption from 01/10/13



## Suggested protocol for paediatric verification

Fraction 1 (Images acquired & auctioned before treatment delivery)	<ul style="list-style-type: none"> <li>Acquire orthogonal image set, minimising dose to critical structures (where possible)</li> <li>If field edge verification is needed, where possible image all treatment fields</li> <li>Assess for and correct gross errors immediately</li> </ul>
Fractions 2 & 3	<ul style="list-style-type: none"> <li>Image orthogonal set</li> <li>Assess each image and correct gross errors for each fraction where necessary</li> </ul>
Action before Fraction 4	<ul style="list-style-type: none"> <li>Calculate the overall systematic error (average of the isocentric set-up error) in each orthogonal direction</li> <li>Apply the systematic set-up error correction</li> </ul>
Fractions 4 & 5	<ul style="list-style-type: none"> <li>If the set-up has been corrected, confirm by repeat imaging (typically two or more fractions)</li> <li>If practical, calculate the new overall systematic set-up error and correct</li> </ul>
Weekly & first day of each phase of treatment plan	<ul style="list-style-type: none"> <li>Image orthogonal set each week</li> <li>Assess each image and correct gross errors for each fraction where necessary</li> <li>If set-up error is greater than the tolerance value, check by repeat imaging (typically two or more fractions)</li> <li>Apply any systematic set-up error correction</li> </ul>
<ul style="list-style-type: none"> <li>Daily verification may be required for treating tumours planned with very small margins or hypofractionated techniques</li> </ul>	
<ul style="list-style-type: none"> <li>Patient immobilisation devices to help maintain treatment position is essential</li> </ul>	
<ul style="list-style-type: none"> <li>Anaesthesia may be necessary for adequate immobilisation</li> </ul>	
<ul style="list-style-type: none"> <li>Concomitant exposures should be especially considered in children and adolescents</li> </ul>	
<ul style="list-style-type: none"> <li>Tolerances and action levels to use will vary, particularly with the immobilisation and treatment technique used as well as compliance of the patient and should be chosen accordingly</li> </ul>	

Anatomical match structures

As per site-specific protocol guidelines

## Additional standards for the provision of Total body irradiation

<b>Service Specification No.</b>	
<b>Service</b>	Total Body Irradiation
<b>Commissioner Lead</b>	
<b>Provider Lead</b>	
<b>Period</b>	12 months
<b>Date of Review</b>	

### 1. Population Needs

#### 1.1 National/local context and evidence base

Total Body Irradiation (TBI) is part of the conditioning therapy of many regimens in common use for patients undergoing haematopoietic stem cell transplant (peripheral blood stem cell transplant, (PBSCT)). TBI contributes to the eradication of tumour cells, particularly from sanctuary sites, and also acts to cause severe immunosuppressant allowing subsequent engraftment of the transplanted stem cells (by preventing immunologic rejection of transplanted bone marrow/PBSC). TBI is used in both the paediatric and adult population.

The conditioning process for bone marrow transplantation/PBSCT is complex and toxic, with a conditioning regime employing chemotherapy/other drugs and TBI prior to the transplant of stem cells. PBSCT results in engraftment of those stem cells in the recipient, the aim being a reconstitution of the recipients' ability to manufacture their own blood and blood borne immune system.

TBI is associated with significant acute and late toxicity. Side effects include mucositis, dysphagia, diarrhoea, parotitis, erythema of the skin, veno-occlusive disease and the attendant risks of prolonged neutropaenia, and even death.

In the longer term, side effects include cataracts, reduced pituitary function, neurologic sequelae, infertility, reduced lung function, increased risk of ischaemic heart disease, and an increased risk of second malignancy.

Patients requiring TBI need specialist counselling, an experienced and coordinated transplanting and radiotherapy team, and expert long term follow up. Radiotherapy departments should have established experience in delivering this treatment, as survival and the risk and types of acute toxicity, and subsequently risk of death, are sensitive to changes in technique (including the use of shielding and dose/dose rate changes).

The radiotherapy department should also be able to offer a service that accommodates patients in a timely manner (as TBI treatments can be twice daily and of prolonged nature which may pose a challenge to scheduling treatments) Larger departments tend to have less of an issue regarding scheduling and also the experience in terms of patient numbers to audit their technique in terms of outcome.

TBI is given within a patient pathway that involves transplanting haematologists and clinical oncologists. The transplant team may or may not be based on the same hospital site as the radiotherapy team and the radiotherapy delivery equipment (Linacs).

## 2. Scope

### 2.1 Aims and objectives of service

For clarity, where reference is made to the transplant team/service this refers to the transplanting haematology team (the 'referrer'). Where reference is made to the TBI team/service, this refers to the team based within the centre delivering the TBI (the 'referred to').

The TBI service encompasses the following:

- Receipt of referrals from transplant teams
- Screening, counselling and consent of patients by the clinical oncologist prior to commencement of TBI
- Scheduling of the TBI treatment to enable timely conditioning for PBSCT
- Treatment of the patient with TBI

Paediatric, Teenage and Young Adult, and Adult patients may require TBI as part of their conditioning process.

It is expected that TBI is delivered to ensure that:

- **Safety:** TBI, as a form of radiotherapy, is delivered according to national standards of quality assurance and that transplant services have documented engraftment rates and transplant related mortality rates through audit. The TBI service should only receive referrals, and be part of, an appropriately JACIE accredited service (see below).
- **Access:** TBI patients have timely access to TBI when required. Scheduling of TBI should not be an impediment to the scheduling of PBSCT.
- **Capacity:** TBI patients should have dedicated access to a Linac and the radiotherapy department should have sufficient capacity to effect timely scheduling (of counselling/consent, planning and TBI delivery)
- **Technology:** TBI delivering departments should have appropriate dosimetry and quality assurance (QA) procedures.

## 2.2 Service description/care pathway

The transplant team should discuss patients in a multi-disciplinary team setting (MDT) prior to referral to the TBI service.

Referral to the TBI team should be timely, to allow for appropriate counselling, consent, and planning/delivery of treatment.

Relevant demographic and clinical detail should be included in the referral, with baseline investigation results appended or an indication as to when they will be done (Pulmonary Function Tests and Echocardiogram). The type of transplantation required should also be indicated (Autograft, Matched Unrelated Donor Transplant, or Sibling Allograft), as well as the TBI dose required according to local/national protocol.

Potential TBI patients (and family for paediatric patients) must be seen by the treating clinical oncologist well in advance of their TBI conditioning. Additionally paediatric and Teenage/Young Adult patients should be seen in an age appropriate environment with appropriate support. This allows for timely informed consent, appropriate screening of patients/families with regards suitability, and timely scheduling

At the initial consultation the following areas should be covered:

- Discussion of the role of TBI in PBSCT
- Review of the patients past medical history to screen the patient for suitability
  - Previous cardiovascular, pulmonary, hepatic and neurological problems in particular
  - Active infections
  - Smoking history
  - Smoking cessation advice if necessary
  - History of previous radiotherapy (if any)
  - Review of baseline echocardiogram and pulmonary function tests (as appropriate)
  - The TBI treatment schedule proposed
- The acute side effects of TBI in the context of PBSCT conditioning including treatment related mortality, should be discussed
- The late side effect profile of TBI
- An information leaflet outlining the TBI process and toxicities should be given to the patient

The radiotherapy team should be familiar with the treatment technique employed at their centre, and be familiar with the acute and late toxicities of TBI.

Each centre should have one nominated consultant clinical oncologist responsible for the service and at least two able to consent patients, plan and prescribe TBI (to provide cover for absence).

There should be a named therapeutic radiographer who coordinates the scheduling of

TBI patients and ensures timely scheduling of patients with dedicated access to a Linac and any planning scans that may be required

Differing techniques are currently in use for the delivery of TBI. Multiple factors influence the choice of technique including; ability to optimise dose homogeneity, accurate delivery, reproducibility, ease of set up, local constraints on field size and room size, whether the facility is dedicated for TBI or is also required for conventional radiotherapy and the availability of CT planning capacity and physics support.

There are currently three broad categories of TBI technique:

- Simple set up using 2 or more fields (not requiring CT planning), with or without lung compensators
- Simple set up with the use of test doses to assess treatment dose distribution prior to treatment dose delivery
- CT planned treatments

No evidence currently exists for the superiority of any one technique and therefore the technique used should be based on the centres experience and resources and should adhere to good practice with regard to QA and dosimetry. Long-term outcome data does exist for simple set up techniques with CT planned techniques aiming to emulate simple set up but with improved dose homogeneity.

Newer radiation delivery techniques are being developed to potentially replace TBI in some instances. Results are promising in some areas, but use of such techniques with the explicit aim of delivering non homogenous radiation dose in the context of transplant conditioning should be done in the context of auditable outcomes

The TBI prescription should at least include the following radiotherapy related information:

- Total dose prescribed to a prescription point (ICRU 50 approved prescription point)
- Number of fractions
- Number of fractions per day
- An indication of the radiation dose to the lungs (most centres will by default prescribe to the lungs or mid thorax which is sufficient)

Once the patient has completed TBI their acute care will continue with the transplant team, with advice from the TBI team as required. The transplant team should receive a treatment summary of the TBI, from the treating clinical oncologist, which includes details of the radiotherapy dose and fractionation used.

Patients who receive TBI require close follow up by the transplant team. Patients who survive long term require dedicated long-term follow up/survivorship care. Follow up protocols must be in place to monitor patients for the late effects of total body irradiation including skin checks (2<sup>nd</sup> malignancy), other 2<sup>nd</sup> malignancies (NB Breast Cancer screening in young women who have received TBI) neuropsychological sequelae, pulmonary function tests, screening for ischaemic heart disease (and

management of non fixed risk factors for ischaemic heart disease), endocrinopathies, and infertility. The transplant team or a dedicated long-term follow up service with sufficient experience of managing such patients should provide the survivorship care.

### **2.3 Population covered**

Paediatric (up to, but not including, 16 years of age), Teenage and Young Adult (16-24 years of age inclusive), and Adult patients (over 25 years of age) may require TBI as part of their conditioning for PBSCT

### **2.4 Any acceptance and exclusion criteria**

Acceptance/Exclusion criteria as dictated by the appropriate clinical transplant protocol.

### **2.5 Interdependencies with other services**

Patients requiring TBI will be primarily under the care of the transplanting service.

With regards to the delivery of TBI, Standard Operating Procedures (SOP) and Service Level Agreements (SLAs) should be in place to define how the service should operate and define the relationship between the transplant teams and the radiotherapy team. Separate SOPs and SLAs should exist for each of the referring transplant teams (Adult and Paediatric).

## **3. Applicable Service Standards**

### **3.1 Applicable national standards e.g.: NICE, Royal College**

**Improving Outcomes in Haematological Cancers' Guidance, published by NICE**  
[http://www.nice.org.uk/nicemedia/pdf/NICE\\_HAEMATOLOGICAL\\_CSG.pdf](http://www.nice.org.uk/nicemedia/pdf/NICE_HAEMATOLOGICAL_CSG.pdf)

- JACIE accreditation of the transplant service is required (whether paediatric, TYA, or adult).
- The guidance states 'High dose therapy with progenitor cell transplantation is to be carried out only in centres which meet JACIE accreditation standards, including the minimum case-load criterion of 10 procedures per annum'. Level of accreditation is dependent upon the nature of transplant work undertaken (Autografts – Level 2, Allografts – Level 3). JACIE accreditation (<http://www.jacie.org>) ensures that a PBSCT service is performing at the required level of excellence, with accreditation based on the entire PBSCT service, including transplanting and TBI services. As patient outcome is highly dependent upon good quality transplant and radiotherapy team coordination and care, referrals for TBI should only be made within an appropriately JACIE

accredited service (the nature of work permitted dependent upon the level of accreditation).

- TBI should only be delivered in centres with a significant caseload and where there is adequate support.
- The guidance states 'TBI...is a specialised technique that should only be given in radiotherapy centres which perform such treatments regularly and have the requisite scientific and physics support'.

**'Improving Outcomes in Children and Young People with Cancer' guidance, NICE (<http://guidance.nice.org.uk/CSGCYP>)**

- For both paediatric and Teenage and Young Adult patients (TYA, from 16- 24 years of age inclusive), services should adhere to the principles set out in the NICE Improving outcomes in children and young people with cancer guidance.
- This Improving Outcomes Guidance (IOG) states the following; 'total body irradiation as part of the conditioning regimen for a haemopoietic progenitor transplant...*the transplant* should only take place in JACIE accredited centres', 'More than one consultant clinical oncologist with appropriate subspecialisation, *and with* membership of the UKCCSG (*now CCLG*). *This* enables consultant cross cover arrangements', 'a lead therapeutic radiographer with specific training and responsibility for treating children and young people', 'Support of a play specialist', and 'Clinical protocols agreed with the Primary Treatment Centre'.

**Childrens Cancer and Leukaemia Group (CCLG) affiliated services/centres**  
**CCLG- <http://www.cclg.org.uk>**

- Paediatric TBI services (for patients up to but not including 16 years of age) should only be delivered in CCLG centres and should only receive referrals from the same (i.e. the transplant service which should be similarly affiliated to the CCLG). The consultant clinical oncologist(s) should also be a member of the CCLG.

#### 4. Key Service Outcomes

The TBI service should show:

- Demonstrable adherence to applicable national standards (applicable to those age groups treated by the TBI delivering centre) i.e. JACIE, NICE, CCLG.
- Demonstrable adherence to national physics QA standards.
- Evidence of Linac capacity to accommodate TBI patients in a timely way (e.g. reserved planning/treatment slots to accommodate anticipated activity etc.)
- Documented evidence of acceptance of appropriately completed referrals from the transplant team
- Documented evidence of timely outpatient screening, counselling and consenting of patients prior to TBI, with at least 48 hours between these duties and the TBI treatment.

- Documentary evidence of appropriately completed TBI prescriptions
- Documentary evidence of adequately completed TBI treatment summaries

The transplant service should show:

- Evidence of engraftment, pneumonitis, and mortality rates for the major haematological diagnoses grouped by major conditioning regimen. Where these are particularly high or low then further analysis should be done to determine whether the TBI technique, or other factor, is responsible

Interim for adoption from 01/10/13

## Additional Standards for the Provision of stereotactic Ablative Radiotherapy

<b>Service Specification No.</b>	
<b>Service</b>	Stereotactic Ablative Radiotherapy (SABR)
<b>Commissioner Lead</b>	
<b>Provider Lead</b>	
<b>Period</b>	12 months
<b>Date of Review</b>	

### 1. Population Needs

#### 1.1 National/local context and evidence base

There is a greater move to delivering radiotherapy using stereotactic radiotherapy techniques.

Nationally; the context supporting delivery is set out in the guidance from the National radiotherapy Implementation Group; (Stereotactic Body Radiotherapy: Guidelines for Commissioners, Providers and clinicians in England 2010).

This guidance sets out that Stereotactic Ablative radiotherapy (SABR) should be provided in the context of clinical trials and clinical studies to ensure that the evidence base for this treatment continues to accrue.

There are data to support the use of SABR in early stage lung cancer, especially as an alternative to surgery for inoperable patients.

It must be noted that there are also commissioning specifications for Stereotactic Radiotherapy (SRT) and Stereotactic Radiosurgery (SRS).

### 2. Scope

#### 2.1 Aims and objectives of service

SABR is a form of external beam radiotherapy using specialised equipment to precisely deliver highly focused radiation to benign or malignant tumours in the body. This technique enables a high dose of radiotherapy to be delivered to tumours in a small number of treatments, whilst sparing the surrounding healthy tissue. It usually requires specialist positioning equipment.

Single fractions delivered to (usually) non-malignant/single/ malignant lesions or malformations are referred to as Stereotactic Radiosurgery (SRS).

SABR can be delivered on multiple platforms; and most SABR is likely to be delivered using Linear accelerators.

It is recommended that SABR not be undertaken at departments treating less than 25 patients over a year with this technique; and be developed as a specialised service (for rarer and complex cases) only at selected centres serving a catchment population of at least 2 million.

## **2.2 Service description/care pathway**

SABR can be delivered in a smaller number of fractions than conventional radiotherapy. This therefore represents a greater opportunity for efficiency gains within the NHS. It must not be forgotten that SABR has a greater requirement of radiotherapy physics time in both planning and service commissioning of clinical radiotherapy delivery. As such, there is perhaps a trade-off of staffing time from treatment delivery to treatment planning and dosimetry. However, greater opportunity for maximising treatment time in radiotherapy can be achieved using SABR techniques.

SABR offers the opportunity for patients who would currently receive treatments which may be prolonged, inconvenient, expensive or associated with significant risk, to be considered for a technique which may involve only 3 or 4 hospital visits with minimal toxicity and with potentially greater disease control rates. It may not only be an alternative to conventional external beam radiotherapy, but also to a range of surgical procedures, and, because the number of visits is so few, it may be very cost effective by comparison.

SBRT is a novel technique, and the fractionation usually utilised is not conventional. Accordingly careful follow up, both in the short- and long- term, is necessary to confirm the efficacy, and to assess early and late toxicity, and assiduous documentation of all outcomes, including early and late effects, is mandatory for any SABR programme.

## **2.3 Population covered**

There are data to support the use of SABR in early stage lung cancer, especially as an alternative to surgery for inoperable patients.

Evidence is beginning to mature in the following sites showing local control, however ongoing studies will develop firm recommendations for its use. In the interim any treatments, other than for early stage lung cancer should be undertaken as part of a clinical trial and include:

- Renal cancer
- Hepatic primary tumours
- Hepatic metastases
- Spinal tumours

- Oligometastases

The following cancers have less clear evidence, although the data may show opportunities:

- Pancreatic cancer (inoperable)
- Prostate cancer
- H&N cancer

There is evidence to support the delivery of SABR from a number of sources. Whether (as present) this data is sufficiently robust to allow it to be presented as a 'standard of care' approach is unclear. Data suggests equivalence rather than improvement in some areas. However; the data is increasingly available to support this direction. There are some cancer sites where SABR clearly has a benefit.

## 2.4 Any acceptance and exclusion criteria

The SABR work force needs to be truly multidisciplinary in its approach. Careful consideration should be given from the outset to the provision of adequate staffing and the education and training of staff in this new technology and associated techniques.

Doses of up to 60Gy in up to 8 fractions (maximum) should be used as per UK SABR guidelines.

Appropriate education and continuing education of professionals directly involved in SBRT procedures should be given a high priority. Training should include QA, planning, treatment delivery and verification technologies and techniques.

Safety considerations should also be included in the training for these new techniques. The training of professionals should involve the 'normal' and 'unusual' circumstances likely to occur in the radiotherapy process.

## 3. Applicable Service Standards

### 3.1 Applicable national standards e.g. NICE, Royal College

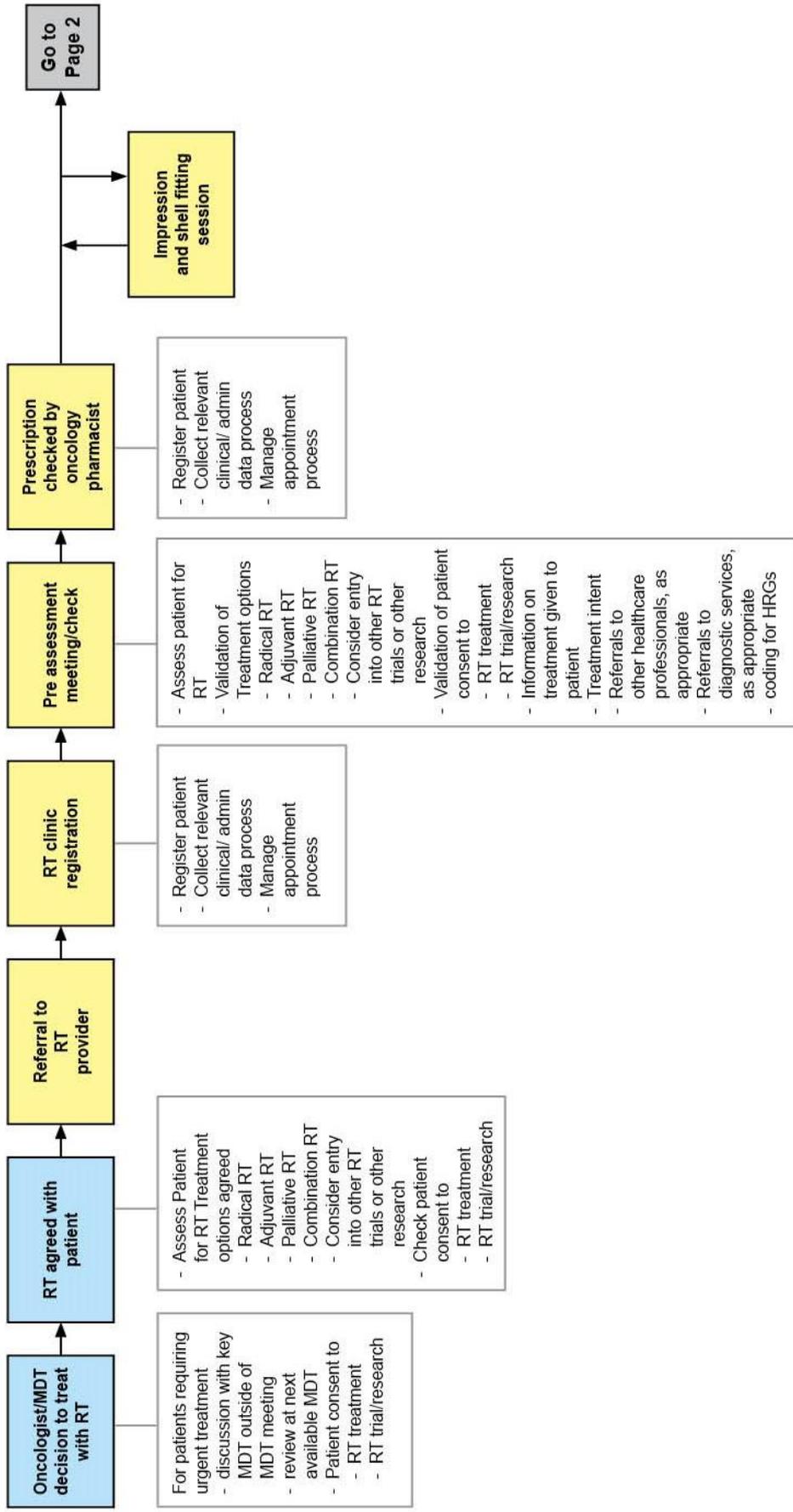
Key guidance is provided in "National Radiotherapy Implementation Group Report

Stereotactic Body Radiotherapy: Guidelines for Commissioners, Providers and clinicians in England 2010"

## 4. Key Service Outcomes

All external beam radiotherapy key service outcomes apply here.

# Generic External Beam Radiotherapy Pathway - Planning Appendix A - Patient Pathway

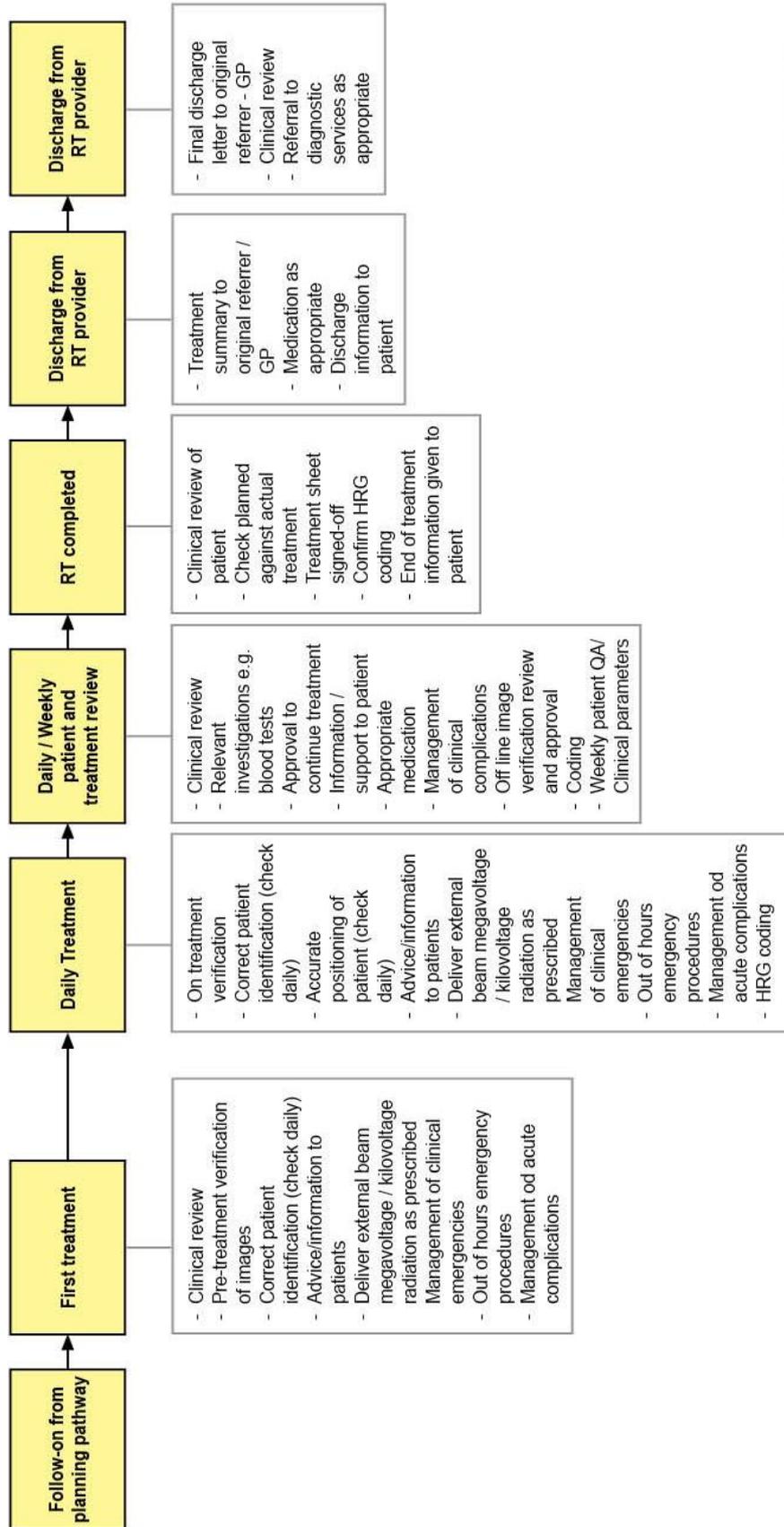


Treatment

parts at /

targets are:

Generic External Beam Radiotherapy Pathway - Treatment  
**Appendix A - Patient Pathway**



**Providers are required to comply with IR(ME)R regulations throughout the pathway**

**Change Notice for Published Specifications and Products  
developed by Clinical Reference Groups (CRG)**

**Amendment to the Published Products**

**Product Name**

Service Specification Radiotherapy All Ages

**Ref No**

B01-Sa

**CRG Lead**

Kim Fell

**Description of changes required**

Describe what was stated in original document	Describe new text in the document	Section/Paragraph to which changes apply	Describe why document change required	Changes made by	Date change made
The key service outcomes table was repeated in the paediatric section of the service specification document in error	The table has been removed	Page 32	The CRG agreed that the measures outlined in the table had been repeated from the main document inappropriately as the measures apply to the radiotherapy service and not to individual patient cohorts. It was agreed to remove them from the document as their inclusion was an error	Kim Fell	18 <sup>th</sup> February 2014