



National Cancer Action Team
Part of the National Cancer Programme

National Radiotherapy Implementation Group Report

Stereotactic Body Radiotherapy

**Guidelines for
Commissioners, Providers and Clinicians
in England 2011**

Foreword

The National Radiotherapy Implementation Group (NRIG) was set up in 2008 to oversee the implementation of the NRAG report.

Its remit has a number of work streams (<http://www.ncat.nhs.uk/our-work/ensuring-better-treatment/radiotherapy>) including supporting the introduction of new treatments and technologies.

The growing role of Stereotactic Body Radiotherapy (SBRT), the increasing number of technologies to deliver it along with the lack of clear national guidance was recognised as an area for action.

NRIG therefore approved a short-life working group to develop and agree national guidance for commissioners and clinicians on the role and opportunities of SBRT.

This group first met in January 2010, and agreed to write and deliver its report back to NRIG by the end of 2010.

Guidance has been written in clear sections, and the ordering of these sections is important. Firstly, guidance for commissioners detailing the areas in which SBRT is deemed an appropriate clinical treatment option; secondly, guidance to providers in setting up an SBRT service; and finally, guidance to clinicians (of all three professional disciplines) in the clinical provision and delivery.

It is a tribute to the input and efforts of all those on this group that we are now able to present this report to the National Radiotherapy Implementation Group on time. Our thanks to all those who gave of their time, knowledge and skills are recognised here.

The clinical guidelines have (where possible) been internationally peer reviewed.

It is expected that this guidance will support commissioners in their planning and commissioning decisions on SBRT and other radiotherapy opportunities.

It is also expected that this guidance will inform clinicians on the development of this significant clinical opportunity.

We recognise that this is a short-life working group; and with the publication of this report, the groups work is complete. However, the opportunities for SBRT continue. We therefore are clear within our recommendations that there should be a consortium of clinicians and commissioners who take an overview of the continuing development of this technology in its wider context. This must be affiliated to one or more of the professional bodies. Its focus must be both on clinical and technical best practice as well as clear advice to commissioners on SBRT.



Dr Peter Kirkbride

Chair

National SBRT Sub-group



Tim Cooper

Associate Director

National Cancer Action Team

Contents

	Foreword	Page 1
	Executive Summary	Page 3
	Introduction	Page 4
Guidance for Commissioners		
	Service Commissioning Guide	Page 6
	Estimates of demand	Page 9
	Tariff and Commissioning Currencies	Page 11
	Commissioning Guidance	Page 12
Guidance for Providers		
	Equipment appraisal	Page 13
	General Cost Evaluation	Page 15
	Workforce	Page 15
Guidance for Clinicians		
	Clinical Reviews of the Evidence	Page 18
	Technology Appraisal	Page 18
	Physics and Quality Assurance	Page 20
	Radiotherapy Physics Commissioning	Page 21
Conclusions		
	Strategy for Implementation	Page 28
	Conclusions	Page 31
	Recommendations	Page 32
Appendix 1	Abbreviations	Page 34
Appendix 2	Glossary	Page 35
Appendix 3	Membership of the working group	Page 36

Executive Summary

Stereotactic body radiotherapy (SBRT) refers to the precise irradiation of an image defined extra cranial lesion associated with the use of high radiation dose delivered in a small number of fractions. The technique requires specialist positioning equipment and imaging to confirm correct targeting. It allows sparing of the surrounding healthy normal tissues.

The treatment can be delivered using standard linear accelerators or using specially designed devices some of which are dedicated solely to this modality of treatment. Specialist teams working to standard operating procedures with detailed quality assurance are essential to safe and effective delivery.

SBRT is more resource intensive than conventional radiotherapy in terms of additional equipment and planning procedures. However, delivery in only a few high dose fractions provides the opportunity for savings.

SBRT is an established treatment for early-stage lung cancer and has been shown in non-randomised studies to be superior to conventional radiotherapy in terms of local control and survival. For selected patients with peripheral tumours who are inoperable because of co-morbidity, technical reasons or patient choice, it offers high rates of local control with low morbidity. It should therefore be available as an alternative to conventional radiotherapy or radical surgery.

SBRT may also have a role in the management of a number of other cancers but the evidence base is less developed and at present treatment can only be recommended in clinical studies, which should therefore be supported by commissioners. This is a rapidly evolving area of medical practice and indications are likely to expand as the evidence base accrues.

Although the basic principles employed in using SBRT are similar to those for all other forms of conventional radiotherapy including IMRT and IGRT, the extreme hypofractionation means that the consequences of any single error would be consequently greater. Accordingly, patient safety is an over-riding factor when delivering an SBRT programme, so assiduous quality assurance programmes must be place, and the professional competences of all members of the treating team must be maintained.

It is recommended that SBRT be:

1. made available to all suitable cancer patients in England, but particularly those with early lung cancer and contraindications to surgery
2. supported by the establishment of a national oversight group to review indications and emerging evidence
3. not undertaken at departments treating less than 25 patients over a year with this technique
4. used to treat patients with head and neck, hepatic and spinal tumours only as a part of a programme at a specialised centre treating significantly larger volumes of patients
5. undertaken only where short and long term outcomes will be reliably assessed
6. made available preferentially to patients as part of clinical studies
7. be available at any centre provided the necessary quality assurance safeguards are in place and with commissioner approval
8. developed as a specialised service (for rarer and complex cases) only at selected centres serving a catchment population of at least 2 million
9. commissioned at a population level at what is current recognised as part of specialised commissioning

Introduction

Stereotactic radiation therapy has been used for benign and malignant lesions in the brain for many years. Stereotactic radiosurgery (SRS) is a single fraction of stereotactic directed radiation of a limited volume in the brain or other structure of the skull base, whereas stereotactic radiotherapy (SRT) has been defined as a fractionated stereotactic directed radiation of a limited volume in the brain. A service specification for cranial SRS and SRT was produced in 2009¹, but it is now acknowledged that there is increasing evidence for the potential benefits of stereotactically directed radiation therapy to structures outside the brain and skull. This has been termed stereotactic body radiotherapy or SBRT.

Being able to accurately define a tumour with pin point multi-dimensional accuracy, targeting that tumour without damaging surrounding tissue, destroying it and curing the patient with just a few radiation treatments is a lofty goal in radiotherapy which is rarely attainable. SBRT moves radiotherapy closer to that goal. With improved imaging and more sophisticated equipment, these goals have been approached by neurosurgeons and oncologists working in tumours of the brain and skull. Stereotactic radio surgery has become increasingly used over the last two decades as improved patient immobilisation and image guided radiation therapy (IGRT) have allowed small tumours in these areas to be accurately ablated, sometimes with only a single dose of radiation treatment.

Recent advances in imaging radiation delivery and patient placement, are now allowing this technique to be extended to tumours elsewhere in the body. There is the potential for a large number of cancers currently being treated by long courses of external beam radiotherapy, which often cause significant side effects, to be treated and cured with shorter courses of more accurate radiotherapy with consequently fewer side effects. Excitingly there is also the potential for tumours which are currently not treatable by conventional methods to also benefit.

There are many potential benefits to patients from using SBRT. It enables delivery of extremely precise high doses of radiation to malignant or benign tumours that are small, may be hard to reach and otherwise inoperable or untreatable. The physical properties of SBRT allow the use of tighter margins, and so less normal tissue is affected with consequently fewer side effects for patients.

At the end of 2009 the National Radiotherapy Implementation Group (NRIG) set up a short life working group to look into SBRT with a view to providing some national guidance, and where possible, a service specification for commissioners. The purpose of this subgroup was to scope the use of SBRT in England, collate the multiple technologies employed, and identify suitable clinical indications and guidance for the role in cancer radiotherapy; it was requested to provide a report to NRIG by the end of 2010.

This work is based on the latest evidence and clinical research available to the group. However, this is an evolving and developing field, and these guidelines must be kept under review.

There are various definitions that exist for SBRT in literature and in common practice. The working group agreed that the definition of SBRT should be as follows:

“stereotactic body radiotherapy (SBRT) refers to the precise irradiation of an image-defined extra-cranial lesion associated with the use of high radiation dose in a small number of fractions”.

It acknowledged that a lay definition should also be provided and the agreed form of this was

‘SBRT 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’.

¹ Service Specification Stereotactic Radiosurgery and Stereotactic Radiotherapy 2009: James Palmer et al. available via National Cancer Action Team

The following document comprises a brief description of the principles of SBRT, and reviews the evidence for its value in certain clinical sites, which include recommendations as to whether or not SBRT should be deemed as being either a standard of care, available for selected patients, potentially beneficial but required further research, or of no proven benefit. There are also sections dealing with physics and quality assurance, workforce implications, providing advice for commissioners, and a review and evaluation of the currently available technologies which are capable of delivering SBRT.

It is intended that this document will provide benefit as a basis for either local or national clinical guidelines, as a tool to aid the service commissioning of SBRT in England (and the rest of the UK) and as guidance to developing a strategy for using SBRT in England (and the UK) in the future.

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 SBRT programme.

Terminology

It is important to note that within this document, the term 'commissioning' has two definitions and two connotations.

Commissioning can be defined as the act of committing healthcare resources with the aim of improving health, reducing inequalities and enhancing patient experience. In the context of this paper, commissioning refers to the arrangement between a purchaser of a service and those responsible for its provision. Its function is greater than contracting and refers to the arrangement where responsibility for quantity sits within a responsibility for acceptable service delivery levels, quality and access. This responsibility currently sits within Primary Care Trusts (PCTs), although in many areas some service commissioning is delegated to Local or Specialist Commissioning Groups.

In the context of a clinical radiotherapy physics service, commissioning refers to those actions required to bring a piece of radiotherapy technology or equipment into clinical use. It is the ultimate responsibility of the Head of Radiotherapy Physics to confirm that a piece of equipment has been satisfactorily commissioned. It requires QA, acceptance measurement and testing of the equipment's capability against its specification (acceptance testing), and ensuring that these measurements are safe to use for treatment planning and service delivery.

To support this we have designated them as service commissioning and physics commissioning where appropriate within the text.

The reader of this document is cautioned to ensure that they are reading this term in the correct context.

A glossary is also included in the appendices to support the non-radiotherapy professional.

Guidance for Commissioners

1.0 Service Commissioning Guide

Note that in this section, 'commissioning' is used in a contractual and service specification context. (see introduction)

1.1 Introduction

- 1.1.1 Commissioners of health care are charged with ensuring that the services they commission are clinically effective, cost effective and represent value for money. Commissioners are also charged with ensuring equity of access for the population for which they commission services. The terms of reference of the national SBRT subgroup charged the group with specifically considering clinical effectiveness.
- 1.1.2 The clinical section of the document gives significant detail of the evidence of clinical effectiveness currently available and is recommended to commissioners and public health advisors. This commissioning section of the guidance will focus on the conclusions from the evidence review.
- 1.1.3 This guidance will give advice for commissioners regarding how SBRT should be considered in relation to other radiotherapy treatment and will advise on the commissioning currency that should be used to compare treatment costs.

1.2 Commissioning Context

- 1.2.1 At the time of producing this guidance the NHS, and particularly the arrangements for commissioning services, is in a state of significant change. There is not yet clarity on which services will be commissioned by GP consortia and which by the National Commissioning Board. However, stereotactic radiosurgery is already defined within the national specialised services definition set and clearly fits the requirements of specialised services commissioning; these being the requirement for a planning population of over 1 million and that the activity is relatively low volume and high cost.
- 1.2.2 It would seem logical then that the responsibility for commissioning stereotactic radiosurgery would sit with the National Commissioning Board. This presents future opportunities for a national commissioning policy. However, transition to the commissioning arrangements is still in the early stages. Stereotactic body radiotherapy is an emerging technology which will not stand still until the new commissioning arrangements are in place. Commissioners will (and already do) receive requests to fund SBRT treatment and it is more than likely that the number of requests will increase over the coming months and years. This guidance is presented in the context of informing existing commissioners of stereotactic radiosurgery about the new technology and aims to enable them to address the issues and maintain business continuity.

1.3 Clinical Context

- 1.3.1 Stereotactic radiosurgery (SRS) for cranial indications is already recognised as a useful method of delivering radiotherapy treatment. There are a number of provider organisations delivering SRS through a variety of technologies, including LINACs and the gamma knife. This method of delivering radiotherapy has had a nationally recognised service specification since 1993 and is commissioned in most areas of England for one or more specific indications.
- 1.3.2 It is clear that clinicians consider that the use of stereotactic radiotherapy for non-cranial indications is the natural evolution of this method of delivering radiotherapy. It is therefore possible that over the coming decades there may be a significant increase in demand for SBRT. This technique would not be applicable to all tumours – many would be just as well

treated with conventional external beam radiotherapy, particularly through the use of intensity modulated radiation therapy (IMRT) and IGRT. It is likely for a proportion of patient and tumours there may be significant benefits to SBRT over conventional treatment. There may also be a cohort of patients who currently are not treatable but may also benefit.

1.4 **Clinical Effectiveness**

Most SBRT can be adequately performed on a conventional Linac with good volumetric in-room imaging for patient set-up. High specification Linacs with a higher isocentre accuracy and smaller MLC could be employed routinely for much of this work. SBRT can be delivered using conformal, static gantry IMRT and rotational IMRT. Some centres specialising in complex SBRT work may find an advantage in a more specific specialist SBRT delivery system.

1.4.1 Commissioners and public health advisors are recommended to review the evidence and recommendations within the clinical section supporting this guidance in detail when determining whether to commission SBRT for a particular indication. This evidence should be updated regularly, but as at 17th December 2010 (as reviewed by the National SBRT group) it supported SBRT activity in the following cancer sites:

- Lung Cancer
- Prostate Cancer
- Head & Neck cancer
- Hepatic cancer
- Renal Cancer
- Oligometastases
- Spinal tumours
- Pancreatic cancer

Evidence for SBRT is rapidly growing, and it is expected that this evidence base will become stronger as this technique develops. There is however already sufficient evidence available currently to recommend that SBRT should be made available as the treatment of choice to some cancer patients in England. Current evidence indicates those with early lung cancer and contraindications to surgery will have superior outcomes. A table summarising the evidence base and the commissioning recommendations is appended below.

Research into the use of SBRT for other indications should be encouraged to maximise the opportunity for improved outcomes from this emerging treatment modality.

SBRT Commissioning Recommendations

Key	
SC	Standard of Care
CO	Clinical option
NR	Not recommended

R	Routinely commissioned
T	Commission within clinical trial or on an individualised basis
N	Not routinely commissioned

Cancer Type	Review Evidence	Commissioning Recommendation
Lung	SC in medically inoperable Stage I CO	R in medically inoperable Stage I T for other indications (Need further work to compare numbers and costs of conventional radiotherapy)
Pancreas	CO	T
Oligometastases	CO	T
Hepatic Metastases	CO	T
Kidney	CO	T
Prostate	CO	T
Head & Neck	CO	T
Liver	CO	T
Spine	CO	T

2.0 Estimates of Demand

Using the published CRUK cancer incidence data (<http://info.cancerresearchuk.org/cancerstats/incidence>), the NRAG 'treatment tree' estimates of proportions of patients suitable for different treatment modalities (www.canceruk.net/downloads/nrag) and applying the recommendations from the December 2010 NRIG SBRT working party evidence review (<http://www.ncat.nhs.uk/our-work/ensuring-better-treatment/radiotherapy>), it is possible to make some predictions about the potential demand for SBRT. However as this not only involves assessing contemporary data but also anticipating future trial results, as well as predicting how clinicians will interpret those results, how providers and commissioners will respond, to what extent patients will accept SBRT and whether or not other and competing treatments may be developed over the next few years, these are estimates which carry a large amount of uncertainty.

Accordingly, for some sites more than one estimate is used – there may be a maximum number, applicable if SBRT became standard of care for all eligible patients, even when as an alternative to surgery, a maximum number if SBRT became the non-surgical standard for appropriate patients, and a more conservative figure, based on an estimate of likely uptake by clinicians, providers and patients.

Lung Cancer

Incidence 32,000 pa in England

- If all early stage operable NSCL cancers were to have SBRT, potentially 11,000 cases pa
- If all early stage medically inoperable NSCLC cases, and applying data from 2009 LUCADA audit, potentially 3,000
- Cautious estimate assuming approx one-third of such cases, 1,000

Prostate Cancer

Incidence 31,000 pa in England

- If all localised prostate cancers suitable for radical treatment were to have SBRT, potentially 10,600 cases pa
- If SBRT were to replace all forms of radical radiotherapy, potentially 5,300
- Cautious estimate, assuming similar numbers to brachytherapy, 1,100

Pancreatic Cancer

Incidence 6,870 pa in England

- If all operable localised cancer treated with SBRT, potentially 2,900 pa
- If all inoperable localised cancer treated with SBRT, potentially 2,500
- Cautious estimate based on approx. 10% suitability of inoperable cases, 250

Kidney Cancer

Incidence 7,000 pa in England

- If all operable localised cancers treated with SBRT, potentially 2,900 pa
- If all inoperable localised cancers treated with SBRT, potentially 80
- Cautious estimate based on half of such cases, 40

For **head and neck, spinal and hepatic primaries**, as the incidence is very low, and the indications are limited, it is thought that numbers eligible for SBRT would be small; perhaps no more than 200-250 pa, and such treatment should only be carried out in specialised centre.

For patients with **oligometastatic disease** (esp. liver, spine, lymph nodes –the numbers would be a little bigger, perhaps up to 500 pa; such treatments might be part of a non-specialised SBRT service (e.g. lung metastases could be treated as part of lung cancer programme), or in conjunction with a stereotactic radiosurgery service for brain metastases, although consideration could be given to delivery in a specialised centre.

Accordingly, a conservative estimate of the number of cases in England that could be suitable for SBRT is approximately 3,200 per year – or around 60-70 cases for a population of one million.

2.1 Conclusion

- 2.2 Evaluating the clinical evidence for commissioning of SBRT is a complex process. There is evidence to support the delivery of SBRT from a number of sources, specifically as the standard of care of care in early stage medically inoperable non-small cell lung cancer. 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 SBRT clearly has a benefit.
- 2.3 Increased evidence will become available from greater use of this treatment.
- 2.4 It is clear that SBRT represents some clear opportunities:

-
- 2.5 SBRT 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 SBRT 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 SBRT techniques.
 - 2.6 Some SBRT can be delivered using a standard Linear Accelerator with high quality dose delivery systems and good imaging. Specialist SBRT equipment is helpful in some cancers, but access to it should not preclude routine SBRT delivery.
 - 2.7 The delivery of SBRT is an evolutionary process. Developing the process requires additional clinical trials and research data. The opportunities from SBRT are great for the world of radiotherapy.

3.0 **Tariffs and Commissioning Currencies**

- 3.1 At present, a national tariff for radiotherapy does not exist. Stereotactic radiosurgery for cranial indications is commissioned at a negotiated rate. For example, Yorkshire and the Humber Specialised Commissioning Group commission gamma knife treatments for a range of indications using the national tariff for the HRG within which the patient would fall should they receive surgical treatment. Most commissioners will have negotiated a local price for existing methods of delivering radiotherapy.
- 3.2 As a tariff for external beam radiotherapy is developed, consideration for developing a tariff for SBRT should be included in this work; or at the very least, identifying an HRG to which SBRT could be attributed.
- 3.3 The following section offers some guidance to commissioners who, having weighed up the clinical evidence, are considering commissioning SBRT for a particular tumour site.

4.0 **Commissioning Guidance**

4.1 Patients who are appropriate for SBRT will fall broadly into one of three groups:

- 1 Those for whom SBRT is a substitute for an existing treatment
- 2 Those for whom SBRT is a treatment additional to other treatment
- 3 Those for whom there would be no other treatment if SBRT was not available

Group 1

4.2 When considering commissioning SBRT as a substitute for an existing treatment, commissioners should determine the currencies used to commission these treatments and, where possible, use the same currencies for commissioning SBRT. As SBRT is considered to be the next evolutionary stage of radiotherapy, providers should be able to furnish commissioners with the appropriate information in the same currencies as the existing forms of radiotherapy they already commission.

4.3 Existing methods of delivering radiotherapy may be commissioned in a variety of ways. If numbers of fractions are used to commission existing modalities, commissioners should be prepared to take the reduced number of fractions likely to be associated with SBRT and the potentially higher staffing costs into consideration when determining the comparability of treatment prices. If radiotherapy is commissioned as part of a block arrangement, there will need to be discussions to determine whether the costs associated with what is likely to be a very small increase in activity will significantly affect these arrangements.

4.4 Commissioners are also advised to determine whether SBRT may be used instead of other treatments, such as chemotherapy or surgical interventions, when considering the relative costs.

It is possible that the capital costs of providing SBRT may be significant. However, as commissioners do not have access to capital funding, commissioning should be confined to addressing the costs of funding the activity. Providers will need to determine whether there is a viable business case for providing the service.

Groups 2 and 3

4.5 Commissioning of SBRT for patients in groups 2 and 3 will, by definition, require additional funding. This represents a clear service development and will be significantly affected by local service priorities and by affordability.

4.6 This guidance has noted that the numbers of patients likely to benefit will be small in the early stages of the evolutions of SBRT. Therefore, it is unlikely that the development of SBRT in several providers within one of the current Strategic Health Authority areas will be cost effective. Where proposals for SBRT service developments are presented to commissioners, they are encouraged to work closely with clinicians and providers to identify the following:

- a. A realistic catchment area for the service agreed with all provider organisations, clinicians and commissioners, subject to catchment area population provisos already stated.
- b. An agreed location for the service
- c. Clear eligibility for treatment criteria
- d. Numbers of patients likely to be treated
- e. Operational arrangements for how providers and clinicians will work effectively together across organisations

4.7 Any such proposals produced will need to take account of the rapidly changing commissioning arrangements currently in progress.

Guidance for Providers

5.0 Equipment Appraisal

5.1 The NRIIG SBRT subgroup met with representatives of radiotherapy delivery system manufacturers (Accuray, Brainlab, Elekta, OSL, Siemens, and Varian) on 2nd July 2010. Each manufacturer presented data indicating the suitability of their equipment to deliver SBRT. This process allowed all members of the group to have a detailed understanding of each delivery system. Following on from this, a comprehensive assessment of the current technology available was made. Delivery systems with similar characteristics were grouped as follows in order to simplify the analysis.

- 1) Traditional linear accelerator with good volumetric in-room imaging system
- 2) Linear accelerator based system specifically adapted for SBRT
- 3) Specialist radiotherapy delivery system

5.2 Each system had individual technical and clinical merits and was considered acceptable for delivering SBRT treatments. However, in many centres the number of patients who would benefit, using current clinical indications, is small and the use of equipment with multiple functionality would be appropriate e.g. category 1). Conversely, centres who specialise in SBRT work may find an advantage in a more accurate system from category 2) or 3) which would also lend itself to other high precision treatment techniques. An analysis of the merits of manufacturer's implementation of techniques is beyond the scope of this document and there may be specific applications that may make one manufacturer technique superior to another. There are also 3rd party systems that can be used in conjunction with that listed below that may enhance SBRT.

Category / Device	Characteristics	Advantages	Disadvantages
1) Elekta Synergy Siemens Oncor/Artiste Varian Clinac	5–10 mm MLC width 1-2mm Isocentre accuracy Volumetric in room imaging Conformal, static gantry or rotational field IMRT	Fairly rapid treatment delivery Inter fraction motion can be managed Use of gating/breathhold to manage intra fraction motion possible	Relatively large isocentre Non coplanar beam limitations Intra fraction motion not accounted for if gating/breathhold not used
2) Elekta Axesse Varian Trilogy/Truebeam	≤ 4mm MLC width 1mm Isocentre accuracy Volumetric in room imaging Conformal, static gantry or rotational field IMRT	Small isocentre Fairly rapid treatment delivery Inter fraction motion can be managed Use of gating to manage intra fraction motion possible	Non coplanar beam limitations Intra fraction motion not accounted for if gating/breathhold not used

2) Brainlab Exactrac Novalis Tx	2.5mm MLC width 1mm Isocentre accuracy Stereoscopic kV in room imaging. Conformal, static gantry or rotational field IMRT.	Fairly rapid treatment delivery Inter and intra fraction motion can be managed. Volumetric Imaging	Non coplanar beam limitations
3) OSL Tomotherapy	Helical delivery of IMRT treatments. Binary MLC. Coplanar only	Very conformal Inter fraction motion can be managed.	Treatment duration > standard linac Intra fraction motion not accounted for
3) Accuray CyberKnife	Robotic delivery of non-coplanar and non-isocentric circular beams Stereoscopic kV in room imaging Beam positioning precision (< 0.12 mm) and <=0.95mm Total System Error (combining imaging, planning, alignment and beam pointing uncertainties)	Very conformal dose delivery Large number of non-coplanar beams for every patient Inter and Intra-fraction motion are managed automatically in every treatment For respiratory motion management: real-time synchronization of beam and target	Longer treatment duration than Linac delivery systems

Conclusion:

SBRT can be adequately performed on a conventional Linac with good volumetric in-room imaging for patient set-up. High specification Linacs with a higher isocentre accuracy and smaller MLC could be employed routinely for this work. SBRT can be delivered using conformal, static gantry IMRT and rotational IMRT. Some centres specialising in SBRT work may find an advantage in a more specific specialist SBRT delivery system.

6.0 **General Cost Evaluation,**

- 6.1 The cost of specialist SBRT systems was in the order of £2m to £3m, depending on the system.
- 6.2 Some specialist SBRT systems were only able to deliver Stereotactic Radiotherapy. (SRS, SRT and SBRT); other systems were able to deliver other forms of external beam radiotherapy in addition to stereotactic radiotherapy. This must be recognised in choosing a delivery system.
- 6.3 Cost evaluation of any equipment must assume that true value for money will be realised when maximum productivity and maximum clinical benefit can be realised from the same system. SBRT has an expanding role; however the numbers at present are not large.
- 6.4 The subgroup has agreed that it is inappropriate to publish individual manufacturer's list prices here. Firstly, they are commercially sensitive to each company; secondly a list price without the detailed technical evaluation is meaningless.
- 6.5 Those centres that are therefore wishing to consider SBRT should contact manufacturers with systems that fit their clinical delivery plans and discuss current list prices and system attributes. The NHS Supply Chain will also be able to support cost effective purchasing.

7.0 **Workforce**

Key Workforce & Safety Recommendations for SBRT

- 7.1 A multidisciplinary working party should be tasked with the development, implementation and maintenance of the SBRT service. To ensure the success of this working party, unambiguous well-structured communication is essential considering the complexity of the processes involved and the multidisciplinary nature of the work¹. Working practices and implementation processes similar to those recommended in the Peer Review Standards (Manual for Cancer Services 2008) for IMRT should be adopted.
- 7.2 Additional resources are needed to implement and maintain an SBRT programme for most centres. 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.

Development and documentation of procedures

- 7.3 As a starting point a prospective risk assessment for introduction of SBRT should be undertaken to minimise risk of error. An agreed plan with a timeline of how SBRT is to be introduced with clearly defined and allocated responsibilities should be drawn before embarking upon this programme.^{1,2,3} A visit to a centre with significant experience of SBRT would be essential in informing this process.
- 7.4 Clear and unambiguous documentation is essential. Evidence-based practice should be used to inform standard protocols and operating procedures which will need to be audited at short intervals once the service begins. All incidents and near miss events should be monitored and used to inform practice.

Staffing and skill levels

7.5 The SBRT work force needs to be truly multidisciplinary in its approach. Tasks should be assigned in relation to competency rather than professional background, so as to maximise the benefits of skills mix⁴. IPEM⁵, RCR⁶ and SCoR⁷ provide guidance on appropriate staffing levels for the radiotherapy workforce. It is widely recognised that most centres will need additional staffing to implement and maintain an SBRT programme.

Training, competence and experience

7.6 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. In addition to the achievement of core qualifications, competence to practise in a particular centre depends on specialised training in local procedures and practices. There is considerable diversity in operational practice and equipment throughout the UK and internationally. This diversity is one of the drivers for local training. ICRP 112⁸ recommends that training should include an understanding of the science involved in the new technology at both clinical and physical levels, specific training in the equipment and techniques to be used, and 'hands-on' training to obtain the necessary competence before being entitled to use the new techniques in the clinical environment.

7.7 More details of the training and qualifications required can be found by referring to professional organisations and regulatory bodies.^{4, 5, 9, 10, 11}

7.8 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 process¹³. In an era of automated and complicated treatment delivery process staff may pay less attention to pertinent treatment details, so an in-depth understanding of the technology and techniques is essential.¹⁴

Example of how SBRT was successfully introduced in one centre

In our case we reviewed the available literature on SBRT as a whole and for the specific site we intended to treat including physics commissioning, quality assurance, treatment planning and delivery. Following the published guidance we produced a physics commissioning plan. A planning study was undertaken which included a risk assessment. We also visited another centre with a lot of clinical SBRT knowledge to learn from their implementation experiences. Verification of the entire treatment pathway helped us write work instructions. We all worked as part of a multi-disciplinary team which meant that we followed good practice. Once the members of the multi-disciplinary team were considered 'experts' and had introduced SBRT then there was programme of competency based training given to others by these local 'experts'.

References

1. The Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, British Institute of Radiology. 2008. *Towards Safer Radiotherapy*. London: The Royal College of Radiologists.
2. National Manual of Cancer Standards 2008
3. IMRT Guidance for Commissioners and Providers www.ncat.nhs.uk
4. The Royal College of Radiologists. 2002. *Breaking the Mould: Roles, Responsibilities and Skills Mix in Departments of Clinical Oncology*. London: The Royal College of Radiologists.
5. Institute of Physics and Engineering in Medicine. 2009. *IPEM Recommendations for the Provision of a Physics Service to Radiotherapy*. London: IPEM. <http://www.ipem.ac.uk/docimages/2840.pdf>
6. The Royal College of Radiologists. 2006. *Guide to Job Plans in Clinical Oncology*. London: The Royal College of Radiologists.
7. The Society and College of Radiographers. 2009. *Radiotherapy moving forward: Delivering new radiography staffing models in response to the Cancer Reform Strategy*. London: SCoR.
<http://doc-lib.sor.org/radiotherapy-moving-forward-delivering-new-radiography-staffing-models-response-cancer-reform-strat-0>
8. ICRP. 2009. *Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies*. ICRP Publication 112. Ann. ICRP 30(4).
9. Society and College of Radiographers. 2007. *Learning and Development Framework for Clinical Imaging and Oncology*. London: SCoR.
http://www.sor.org/public/pdf/sor_learning_and_development_framework.pdf
10. The Royal College of Radiologists. 2007. *Structured Training Curriculum for Clinical Oncology*. London: The Royal College of Radiologists.
<http://www.rcr.ac.uk/docs/oncology/pdf/CurriculumCOFINALJanuary2007pdf.pdf>
11. Institute of Physics and Engineering in Medicine. 2002. *Guidelines for the Provision of a Physics Service to Radiotherapy*. London: IPEM. <http://www.ipem.ac.uk/docimages/825.pdf>
12. The Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine. 2008. *A Guide to Understanding the Implications of the Ionising Radiation (Medical Exposure) Regulations*. London: The Royal College of Radiologists.
13. Boadu M & Mohan Rehani M. 2009. Unintended exposure in radiotherapy: Identification of prominent causes. *Radiotherapy and Oncology*. (93)609-617.
14. Marks L et al. 2007. The impact of advanced technologies on treatment deviations in radiation treatment delivery. *International Journal Radiation Oncology, Biology & Physics*. 69(5) 1579-1586.

Guidelines for Clinicians

8.0 Clinical Reviews of the Evidence for SBRT

8.1 SBRT is being used throughout the world for several types of tumours in various sites based on various degrees of evidence of benefit. On-going research is therefore being pursued in many areas to try and define the place of SBRT as treatment for certain malignant tumours in the future.

8.2 The NRIG subgroup agreed that they should review the evidence and make recommendations for the following sites:

- Lung cancer
- Prostate cancer
- Head and neck cancers
- Kidney cancer
- Pancreatic cancer
- Tumours of the liver
- Tumours of the spine
- Oligometastatic disease

8.3 The clinical guidelines and documentation that support this review have been subject to national and international review.

8.4 The NRIG SBRT group are grateful to all who gave their time to ensure that this document reflects contemporary and evidence based thinking.

8.5 The specific guidelines are attached separately as individual guidance to ensure they can be updated and refreshed as appropriate. Those using them are encouraged to check the source documentation regularly to ensure they are using the latest version.

9.0 Technological appraisal

9.1 Stereotactic body radiation therapy (SBRT) can be distinguished from conventional radiotherapy by its use of large biologically effective doses delivered in a few fractions. These large doses can be delivered without excessive normal tissue toxicity because SBRT is used to treat fairly small planning target volumes (PTVs) and rapid dose fall-off is achieved beyond the target. Thus SBRT treatments comprise a number of generic features:

- fairly small tumour sizes (typically less than 5 cm);
- tight margins between the clinical target volume (CTV) and planning target volume (PTV), to keep the PTV small;
- rapid dose fall-off beyond the PTV and some peaking of dose towards the PTV centre;

-
- relatively large numbers of treatment fields (either conformal, static IMRT or rotational IMRT), some of which may be non-coplanar, both to conform the high dose region tightly to the PTV and to spread dose out beyond the PTV.

9.2 It follows that SBRT planning, delivery and accessory systems should provide certain capabilities –

- a) The ability to deliver relatively high doses (≥ 6 Gy) at each fraction, using several (5 or more) angularly-spaced fields.
- b) A narrow beam penumbra.
- c) In-room immobilisation, imaging, tracking and/or gating, to minimize or compensate for tumour movement and set-up errors, allowing small CTV-PTV margins to be used without high rates of geographic miss.
- d) Accurate calculation of small radiation field dose-distributions and of tissue inhomogeneity effects by the treatment planning system (TPS).

9.3 For some target sites, additional capabilities may also be advantageous –

- e) Potential to deliver substantially non-coplanar fields from a very wide range of angles.
- f) Delivery of arc-based intensity-modulated dose-distributions ('rotational IMRT').
- g) High resolution field-shaping, using a multileaf collimator (MLC) with a leaf width of 5 mm or less.

9.4 An institution's choice of system will reflect the mix of sites to be treated using SBRT. The core capabilities (a-e), and also (g), can be provided by conventional clinical linear accelerators (linacs) coupled with high-resolution MLCs, modern TPSs, and accessory immobilisation, imaging, tracking or gating technology. A substantial literature exists reporting SBRT treatments carried out using linac-based systems, particularly for targets in the lung and liver.

9.5 In contradistinction to SBRT systems based on conventional linacs, some systems have been engineered to enhance aspects of delivery – particularly capabilities (e) and (f). Consequently these systems may be preferred if it is considered important to deliver a wide angular range of non-coplanar fields, or to deliver rotational IMRT, or if the purchasing institution prefers the accessory imaging/immobilisation equipment provided with these new systems. It may be noted, however, that non-coplanar fields can be delivered across quite a wide angular range using conventional linacs, and that planning and delivery software can be purchased for these conventional systems which enable them also to deliver forms of rotational IMRT.

10.0 **Physics and Quality Assurance**

Key Point Summary

- 10.1 Reference dosimetry is an evolving science in this area. Alanine dosimetry is recommended.
- 10.2 Consistent definitions are fundamental between systems and processes.
- 10.3 Ensure detectors are suitable for field size being measured. Corroboration of data by different methods is vital.
- 10.4 Reproducibility is important. Use of immobilisation where movement may occur must be used.
- 10.5 The ITV and PTV margins must allow for movement for which it is not possible to compensate.
- 10.6 There should be a robust solution to the problem of organ motion appropriate to the site being treated.
- 10.7 TPS algorithms must be suitable for SBRT purposes.
- 10.8 Planning studies are important to ensure operator skills are consistent.
- 10.9 A clear work instruction should be available.
- 10.10 A class solution should be prepared for each site.
- 10.11 IPEM 94 should be followed for Linac QA.
- 10.12 A high quality image guidance system must be employed. Experience in IGRT techniques is necessary.
- 10.13 Inter-centre comparison audits before beginning SBRT should be used.
- 10.14 Regular audit of SBRT must be undertaken.

11.0 **Recommendations for Stereotactic Body Radiotherapy Physics Commissioning**

Note that in this section, 'commissioning' is used in a scientific context. (see introduction)

11.1 This document has been produced to provide a reference for UK centres setting up SBRT and is based on the commissioning at several centres. It focuses on issues relating specifically to SBRT and assumes that all equipment and software is commissioned for standard radiotherapy. There is limited guidance on commissioning SBRT (Potters *et al.* (2004), Kavanagh and Timmermann (2005)) although Benedict *et al.* (2010) gives some recent useful guidelines. Special commissioning and quality control is required to perform SBRT as it involves a small number of fractions with small fields.

11.2 Reference ('absolute') dosimetry

The determination of reference dose in small and composite fields is complex and national and international guidance is still evolving (Alfonso *et al.* (2008), Palmans (2010), Aspradakis *et al.* (2010)). The use of alanine dosimetry (or equivalent) to check reference dose is strongly recommended (Duane *et al.* (2007)) and it is suggested that a national programme is set up, using an appropriate accredited service such as the NPL.

11.3 Commissioning of small MV photon fields

The specific dosimetric and other data required for the commissioning of treatment planning systems (TPS) and monitor unit (MU) check software will depend on the system to be used and manufacturers' guidance should be followed. The definition of field size must be consistent between the treatment machine and the TPS, and should follow the IPEM guidance (Aspradakis *et al.* (2010)). Careful consideration should be given to the choice of detectors used because many are too large for use in small fields and the choice also depends on the quantity to be measured. It is recommended to use more than one type of detector and to corroborate measurements. Recommendations of good working practice for the determination of dosimetric parameters in small MV photon dosimetry are provided in IPEM report 523 (Aspradakis *et al.* (2010)).

For small field output factor measurements, the sensitive region of a detector used MUST be smaller in cross-section than the area of the field being measured excluding the penumbra region that lies within the field edge, otherwise the dose measured will be an average across a highly varying dose-profile, rather than an accurate measure of the dose at the centre of the field.

11.4 Immobilisation

Historically bodyframes were required but the advent of volumetric imaging has meant that frameless techniques can be used. Benedict et al (2010). When making the choice of immobilisation particular consideration should be given to patient comfort and reproducibility as the patient may be on the treatment couch longer than for standard radical treatment. There should be confidence in the accuracy and reproducibility of any system that is used.

Setup error is usually considered to be a shift of the patient bony anatomy away from its planned position relative to the linac coordinate system, with internal movement being changes in soft tissue position relative to the bony anatomy. Thus setup error can be detected using imaging suitable for localising bone (planar kV or MV is often sufficient) whereas to detect internal movement of the target, volumetric soft-tissue imaging is desirable. The Internal Target Volume (ITV) is determined by expanding the CTV to allow for movement (in lung, often simply by adding together CTVs at different phases of the breathing cycle), while the PTV is an expansion of the ITV to allow for setup error.

A study should be carried out to quantify the magnitude and direction of patient setup shifts determined by soft tissue matching to planning CT for the chosen method of immobilisation. Random and systematic set-up errors should be determined to provide an indication of the expansion margin that should be used between ITV and PTV. The true setup error for SBRT patients may be impossible to assess in advance because the treatment/verification technique will be different to standard radical plans (RCR (2008)). When tracking is used some patient movement will be compensated for, however, the tracking system may not correct for motion in all directions and appropriate margins will need to be determined.

11.5 Treatment Planning

a. Tumour Motion Assessment

There are several methods for assessing or accounting for tumour motion. Any system that is employed needs to be fully evaluated and checked prior to its use. For centres treating sites with significant motion due to breathing 4DCT planning is recommended to accurately assess tumour motion. Other alternatives include Slow-CT, Fluoroscopy + CBCT verification. For some tumour sites implantation of markers may be the most appropriate method of assuring that there is not a geographical miss. It is the individual centres responsibility to commission and test the accuracy and reproducibility of their chosen system. It is beyond the scope of this document to cover the commissioning of all tumour motion assessment systems

b. Treatment planning calculations

A TPS commissioned for conformal radiotherapy employing large fields cannot be expected to perform as well in small fields (typically less than 4cm × 4cm) which are used in SBRT. Dose and monitor unit calculations for SBRT should be carried out with sophisticated algorithms which can accurately account for the effects of tissue heterogeneities (3D dose kernel models, or pencil beams if extended to account for tissue inhomogeneity effects on both radiological depth AND lateral scatter) Knöös *et al.* (2006)). Small field data generated by the TPS (dose distributions as well as MU/Gy) should be carefully verified before use (AAPM (2004), NCS (2006), IAEA (2004))

11.6 Treatment Planning Study.

A planning study should be performed on patient scans that would be suitable for SBRT. This will ensure that operators have experience with a variety of types of plans before performing a real patient plan and also that in house work instructions can be written to aid the planning. Volumes should be outlined on at least 3 eligible patient scans for the purposes of testing. For each tumour site a class solution needs to be designed which achieves the relevant dose constraints. Consideration of the position of the isocentre (for linac based systems) should be given to enable the most appropriate imaging to be performed. This may require an offset of the isocentre within the volume to enable appropriate imaging. The complexity of planning will depend on the tumour location and proximity to OARs. Care must be taken to evaluate all CT slices with radiation dose, especially if non-coplanar beams are used. Using this class solution, establish a protocol including choice of TPS algorithm, beam arrangement and plan check procedure.

If the algorithm type used in stereotactic radiotherapy is different to that used on the 'main' departmental planning system, care should be exercised when considering the dose to be delivered. This will be particularly challenging for regions involving inhomogeneities e.g. lung. The independent MU check tolerances will need to be investigated as any relatively simplistic MU check will struggle to obtain accurate results with the combination of small beam size and tissue inhomogeneities. An option may be taken to transfer the plans to another TPS to confirm the dose or calculate on an alternative algorithm that has been validated for use for this type of plan.

11.7 Linac/Specialised Delivery System QA

The current generation of linear accelerators has been designed for conformal therapy rather than SBRT. When extending the use of these linacs for the delivery of small fields as in SBRT,

emphasis must be placed on the calibration of the collimating devices and their alignment with the source. Quality control checks appropriate to a higher required tolerance are then needed to maintain positional accuracy and thus allow confident use of narrow collimated fields. This is as important as the choice of appropriate detector system. It is recommended to follow existing published guidance on QA for delivery equipment as given in IPEM report 94 (Kirby *et al.* (2007)), the report of the AAPM task group 142 (Klein *et al.* (2009)); and the report of the AAPM task group 106 on accelerator beam data commissioning (Das *et al.* (2008)).

For conventional delivery systems many machine-years of treatment experience have been gathered around the world, and consequently the types, chances, and frequencies of failure of these systems are well characterized and reflected in existing QA schedules. However for newer delivery systems (and new subsystem add-ons to existing systems) machine experience is inevitably more limited, and this should be reflected by an enhanced level of vigilance in the QA schedules used by centres adopting these technologies, and it should be noted that combining subsystems produced by more than one manufacturer potentially raises system-integration issues which should again be reflected by enhanced QA vigilance.

11.8 Image Guidance

SBRT requires the use of MV or KV volumetric imaging on the linac and the matching of these images to the reference localisation CT is critical. The coincidence of the volumetric imaging isocentre to the linac MV radiation isocentre is critical. For some tumour sites markers may be implanted close to the tumour and used as surrogates for localising the tumour. Experience should be gained in image matching and IGRT techniques for conventional radiotherapy patients before implementation with SBRT. As SBRT is time-consuming further monitoring may be employed that track points on the patient skin during the treatment. Checks should be performed to demonstrate that these techniques are a suitable surrogate for tumour location.

11.9 Plan Delivery Checks

A check of the dose delivered to the centre of the PTV and confirmation of the dose distribution must be carried out prior to clinical implementation of SBRT. This requires that the patient plan be copied to a phantom for direct dose measurement. The plans generated during the planning study are ideal for this purpose.

The dose to the centre of the PTV is best confirmed with an ion chamber measurement in a suitable phantom in a similar manner to IMRT. Dose delivered to a point from the entire plan should be within a specific tolerance of that calculated by the TPS e.g. $\pm 3\%$ (James *et al* (2008)). Validation of the dose distribution should involve measurement in each off-axis direction, either using a 3D detector array, a series of film measurements or different configurations of 2D detector arrays. Alternatively, EPID dosimetry may be used if commissioned within the centre. The measured dose should agree with that calculated by the TPS for 90% of points using an appropriate gamma pass criteria (Low *et al.* (1998), James *et al* (2008), Bedford (2009)). Further measurements of dose distribution may be done in a phantom that mimics a moving tumour within lung where appropriate. Once confidence in the dosimetry has been established then patient specific measurements are no longer required, but this would require evidence from a substantial series of satisfactorily treated patients.

11.10 External verification

It is recommended that another centre with an established SBRT programme audits centres prior to performing patient treatments. The audit should include a systematic test of all aspects of the programme, including as a minimum a calculation of a typical patient in the treatment planning system and the delivery of this plan to a phantom. Any data transfer and preparation should ideally be performed by the staff who will be involved when treatment is delivered. Consideration should be given to including imaging within this process if possible.

References

- AAPM, Ed. (2004). AAPM TG85: Tissue inhomogeneity corrections for megavoltage photon beams. Madison, Medical Physics Publishing.
- Alfonso, R., Andreo, P., Capote, R., Huq, M. S., Kilby, W., Kjall, P., Mackie, T. R., Palmans, H., Rosser, K., Seuntjens, J., Ullrich, W. and Vatnitsky, S. (2008). "A new formalism for reference dosimetry of small and nonstandard fields." *Med Phys* 35(11): 5179-86.
- Aspradakis, M. M., Byrne, J. B., Palmans, H., Conway, J., Rosser, K., Warrington, A. P. and Duane, S. (2010). IPEM report 523: 'Small MV photon dosimetry', IPEM, *in press*.
- Benedict et al (2010). Stereotactic body radiotherapy: The report of AAPM Task Group 101. *Med. Phys.* 37 (8) p4078-4100
- Bedford et al, (2009) "Evaluation of the Delta4 phantom for IMRT and VMAT verification" *Phys Med Biol*, **54** N167 – N176)
- Das, I. J., Cheng, C. W., Watts, R. J., Ahnesjö, A., Gibbons, J., Li, X. A., Lowenstein, J., Mitra, R. K., Simon, W. E. and Zhu, T. C. (2008). "Accelerator beam data commissioning equipment and procedures: report of the TG-106 of the Therapy Physics Committee of the AAPM." *Med Phys* 35(9): 4186-215.
- Duane, S., Palmans, H., Sharpe, P. and Vynckier, S. (2007). Traceability and absorbed dose standards for small fields, IMRT and helical tomotherapy. Workshop on "Absorbed Dose and Air Kerma Primary Standards", Paris, France, 9-11 May 2007.
- IAEA (2004). TRS 430: Commissioning and quality assurance of computerized planning systems for radiation treatment of cancer. Vienna, International Atomic Energy Agency, ISBN 0074-1914.
- James, H *et al*, Eds. (2008). IPEM Report 96: Guidance for the clinical implementation of intensity modulated radiation therapy.
- Galvin, J M, Bernarz G. Quality Assurance Procedures for Stereotactic Radiotherapy *Int J Radiat Oncol Biol Phys.* (2008) 71(1) pS122-S125
- Kavanagh, B. D. and Timmermann, R. D., Eds. (2005). Stereotactic Body Radiation Therapy. Philadelphia, Lippincott Williams & Wilkens.
- Kirby, M., Ryde, S. and Hall, C., Eds. (2007). IPEM Report 94: Acceptance Testing and Commissioning of Linear Accelerators, Institute of Physics and Engineering in Medicine.

-
- Klein, E. E., Hanley, J., Bayouth, J., Yin, F. F., Simon, W., Dresser, S., Serago, C., Aguirre, F., Ma, L., Arjomandy, B., Liu, C., Sandin, C. and Holmes, T. (2009). "Task Group 142 report: quality assurance of medical accelerators." *Med Phys* 36(9): 4197-212.
- Knöös, T., Wieslander, E., Cozzi, L., Brink, C., Fogliata, A., Albers, D., Nystrom, H. and Lassen, S. (2006). "Comparison of dose calculation algorithms for treatment planning in external photon beam therapy for clinical situations." *Phys Med Biol* 51(22): 5785-807.
- Low, D. A., Harms, W. B., Mutic, S. and Purdy, J. A. (1998). "A technique for the quantitative evaluation of dose distributions." *Med Phys* 25(5): 656-61.
- NCS (2006). Report 15: Quality assurance of 3-D treatment planning systems for external photon and electron beams. Delft, The Netherlands, Netherlands Commission on Radiation Dosimetry.
- Palmans, H. (2010). Progress report of an international working group on Small and Composite Field Dosimetry. IPEM Scope. York, Century One Publishing LTD. 19(2).
- Potters, L., Steinberg, M., Rose, C., Timmerman, R., Ryu, S., Hevezi, J. M., Welsh, J., Mehta, M., Larson, D. A. and Janjan, N. A. (2004). "American Society for Therapeutic Radiology and Oncology and American College of Radiology practice guideline for the performance of stereotactic body radiation therapy." *Int J Radiat Oncol Biol Phys* 60(4): 1026-32.
- The Royal College of Radiologists, Society and College of Radiographers, The Institute of Physics and Engineering in Medicine. *On target: ensuring geometric accuracy in radiotherapy*. London: The Royal College of Radiologists, 2008. ISBN 978-1-905034-33-8.

Strategy for Implementation of SBRT

- 12.0 An informal survey of the English radiotherapy centres showed that the majority of them were not offering SBRT in 2010. Some centres were offering SRS/SRT for brain and skull tumours and several centres contemplating the use of SBRT for one or more extra cranial site groups, but only 5 centres were actually delivering SBRT, and in those centres it was almost exclusively for lung tumours. It can be argued that SBRT is simply a technique which comes out of the natural evolution of radiotherapy as it becomes more sophisticated, very much as IMRT and IGRT followed on from conventional and 3D conformal radiotherapy. However there is also a case to be made for having specialised SBRT centres which would deliver all the stereotactic treatments for certain indications, possibly using dedicated SBRT specific machines. If centres wished to pursue their own SBRT programmes, in most cases it would seem cost effective to use equipment which allows the flexibility to switch between SBRT and conventional radiotherapy treatment. Alternatively, some centres might wish to develop expertise in SBRT in many sites, and/or to set themselves up as national or regional centres for SBRT using dedicated equipment. Although we would not discourage this, based on the evidence contained in this document, it is clear that in most sites SBRT is developmental, and therefore a significant proportion, if not most, of the workload on any SBRT dedicated machine would have to be treated in a research and development setting, if the treatment unit was to be whole-time NHS.
- 12.1 There are successful examples of groups of centres interested in SBRT in one or more body sites working together to perform clinical trials. One example of such a group already in existence in the UK is the National Lung SBRT Consortium. It is recommended that a National Oversight Group for SBRT be established that encompasses all body sites. This group should take the lead on establishing evidence-based prospective treatment protocols. This would produce a common dataset that would enable meaningful analysis of outcomes. Such a group would require administrative support to achieve its function.
- 12.2 It is a clear recommendation of this report that this oversight group should lead on appropriate clinical development, research and inter-professional working. This group should focus on SBRT in its widest context. This group should be affiliated through one or more of the professional bodies (and have clear reporting representation from the others) to ensure that their work is embedded within a framework.
- 12.3 Development of SBRT services must be part of a planned service commissioning strategy from the outset. Given the recommendation from this document that SBRT must be seen as an on-going evaluation of this emerging technology, early commissioner engagement is essential.

-
- 12.4 Ideally the development of SBRT should be managed at Specialised Commissioning level to ensure that this technology (including treatment/audit/trials etc) is well co-ordinated.
- 12.5 Any strategy for implementation for SBRT must be formulated with commissioner input. It is also recommended that, as many of the resources required for intracranial SRS are similar to those required for SBRT, both need to be considered. There is a potential for both to be developed in tandem, where appropriate, and collaboration with commissioners to develop both these services provides the potential for both services to be enhanced, and efficiency maintained.
- 12.6 It is envisaged that SBRT would be most effectively utilised through the use of integrated clinical networks ensuring that those patients who were suitable for SBRT were properly assessed by a multi-disciplinary team, and had access to the appropriate treatment delivered as part of a regional or local service.
- 12.7 It is acknowledged that although the basic principles employed in using SBRT are similar to those for all other forms of conventional radiotherapy including IMRT and IGRT, the use of the extreme hypofractionation means that the consequences of any single error would be consequently greater. According patient safety is an over-riding factor when delivering an SBRT programme and it is recommended that no department treating patients with SBRT should treat less than 25 patients over a year with this technique in order to maintain the professional competences of all members of the treating team.
- 12.8 SBRT may be made be available at any centre provided that the necessary quality assurance safeguards are in place, activity of at least 25 patients per year is maintained, and that prior commissioner approval has been obtained.
- 12.9 Specialised SBRT services for rarer and complex cases (e.g. head and neck, spinal and hepatic tumours) should be developed only at selected centres serving a catchment population of at least 2 million. It is not possible at this time to detail the scope of such specialised services but it is envisaged that as evidence emerges in certain tumour sites there will be some clinical indications where SBRT is indicated albeit for a comparatively few number of patients per year. It is expected that the national oversight group would work with specialised commissioners in leading on defining specialist programmes.
- 12.10 SBRT offers the opportunity for patients who would currently receive treatments which may be prolonged, inconvenient, and 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.

12.11 In addition there is also the opportunity for patients who currently cannot be considered for treatments, both radical and palliative, to have the opportunity of a relatively non-toxic and short course of treatment which may improve their outcomes either in terms of survival, palliation or quality of life. It is acknowledged that in these circumstances SBRT would be a new treatment rather than replacing or substituting for existing therapies, and as such would be an additional cost burden on the NHS. However it may well be that SBRT has the greatest role to play in these situations, for example enabling patients currently considered to be inoperable, to be both treated and cured. ‘Improving Outcomes – a Strategy for Cancer’² 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’, and this guidance is consistent with that direction.

12.12 There is sufficient evidence available currently to recommend that SBRT should be made available as the treatment of choice to some cancer patients in England. Current evidence indicates those with early lung cancer and contraindications to surgery will have superior outcomes, and that research into the use of SBRT for other indications should be encouraged.

12.13 Services undertaking SBRT should be clear about their participation in national and local audit of their work; and the resources to commit to this should be identified at the outset.

12.14 The national SBRT oversight group should lead on the development of an interdepartmental audit programme (consistent with existing practice in other areas of dosimetry) to support this work.

² Improving Outcomes – a Strategy for Cancer DH 2011: www.dh.gov.uk/publications

Conclusions

- 13.0 Stereotactic body radiotherapy (SBRT) refers to the precise irradiation of an image defined extra cranial lesion associated with the use of high radiation dose delivered in a small number of fractions. The technique requires specialist positioning equipment and imaging to confirm correct targeting. It allows sparing of the surrounding healthy normal tissues.
- 13.1 The treatment can be delivered using standard linear accelerators or using specially designed devices some of which are dedicated solely to this modality of treatment. Specialist teams working to standard operating procedures with detailed quality assurance are essential to safe and effective delivery.
- 13.2 SBRT is more resource intensive than conventional radiotherapy in terms of additional equipment and planning procedures. However, delivery in only a few high dose fractions provides the opportunity for savings.
- 13.3 SBRT is an established treatment for early-stage lung cancer and has been shown in non-randomised studies to be superior to conventional radiotherapy in terms of local control and survival. For selected patients with peripheral tumours who are inoperable because of co-morbidity, technical reasons or patient choice, it offers high rates of local control with low morbidity. It should therefore be available as an alternative to conventional radiotherapy or radical surgery.
- 13.4 SBRT may also have a role in the management of a number of other cancers but the evidence base is less developed and at present treatment can only be recommended in clinical studies, which should therefore be supported by commissioners. This is a rapidly evolving area of clinical practice and indications are likely to expand as the evidence base accrues.
- 13.5 Although the basic principles employed in using SBRT are similar to those for all other forms of conventional radiotherapy including IMRT and IGRT, the use of extreme hypofractionation means that the consequences of any single error would be consequently greater. Accordingly, patient safety is an over-riding factor when delivering an SBRT programme, so assiduous quality assurance programmes must be in place, and the professional competences of all members of the treating team must be maintained.

Final Recommendations

14.0 Recommendations

- 14.1 Ideally the development of SBRT should be managed at Specialised Commissioning level to ensure that this technology (including treatment/audit/trials etc) is well co-ordinated.
- 14.2 Services seeking to begin a programme of Stereotactic Body Radiotherapy, either for a new service or for a new clinical indication, must seek early commissioner input and agreement to the programme.
- 14.3 The clinical guidelines and evidence review remains valid at the time of publication. However; SBRT is an evolving treatment process. Those working within this field, or planning to do so, should review the latest literature to support their clinical practice.
- 14.4 The evidence base for SBRT is growing. To support this it is recommended that all patients are treated in the context of a clinical study using a defined protocol to ensure that these data continue to evolve.
- 14.5 SBRT is a novel technique, and the fractionation usually utilised is not conventional. Accordingly careful follow up by an oncologist, both in the short and long term, is necessary to confirm the efficacy, and to assess early and late toxicity. This should include early post treatment follow-up, as acute toxicity in hypofractionation will occur early after treatment completion. Assiduous documentation of all outcomes, including local control of the cancer, early and late effects, is mandatory for any SBRT programme. This will add to the growing pool of information to support improved practice.
- 14.6 The key point summary from section 10.0 is vital for accurate technical delivery
- 14.7 SBRT is delivered within a multi-professional workforce and requires clear clinical protocols and standard operating procedures.
- 14.8 It is recommended that a National Oversight Group for SBRT be established that encompasses all body sites. This group would take the lead on establishing evidence-based prospective treatment protocols, to produce a common dataset that would enable meaningful analysis of outcomes, and should work with the NCRI to develop national trials. This group should be affiliated to a national body.
- 14.9 No department treating patients with SBRT should treat less than 25 patients over a year with this technique, in order to maintain the professional competences of all members of the treating team.

-
- 14.10 SBRT should only be used to treat patients with rarer and complex tumours (e.g. head and neck, hepatic and spinal tumours) as a part of a programme at a specialised centre serving a catchment population of at least 2 million.
- 14.11 SBRT services should be commissioned at a population level at what is currently recognised as part of specialised commissioning.
- 14.12 There is sufficient evidence available currently to recommend that SBRT should be made available as the treatment of choice to some cancer patients in England. Current evidence indicates those with early lung cancer and contraindications to surgery will have superior outcomes, and that research into the use of SBRT for other indications should be encouraged.
- 14.13 SBRT will most effectively be utilised through the use of integrated clinical networks ensuring that those patients who were suitable for SBRT were properly assessed by a multi-disciplinary team, and had access to the appropriate equipment delivered either locally if available or regionally if not.

Abbreviations

CBCT	Cone Beam CT
CTV	Clinical Target Volume
EPID	Electronic Portal Imaging Device
Gy	Gray – a unit of radiation dose measurement
IGRT	Image Guided Radiotherapy
IMRT	Intensity Modulated Radiotherapy
IPEM	Institute of Physics and Engineering in Medicine
ITV	Internal Target Volume
MLC	Multileaf Collimator
MV	Megavoltage
MU	Monitor Units
NRAG	National Radiotherapy Advisory Group
NRIG	National Radiotherapy Implementation Group
PTV	Planning Target Volume
QA	Quality Assurance
RCR	Royal College of Radiologists
SBRT	Stereotactic Body Radiotherapy
SRS	Stereotactic radiosurgery
SRT	Stereotactic Radiotherapy
TPS	Treatment Planning System

Glossary

CTV	<p>Clinical Target Volume</p> <p>The clinical target volume (CTV) is a tissue volume that contains a demonstrable Gross Tumour Volume and/or is considered to contain microscopic, subclinical extensions at a certain probability level.</p>
EPID	<p>Electronic Portal Imaging Device</p> <p>A device by which set-up accuracy can be monitored. By use of an EPID, on-line digital port images may be efficiently captured and analysed before, or even during, every treatment session.</p>
Gy	<p>Gray – a unit of radiation dose measurement</p>
IGRT	<p>Image Guided Radiotherapy</p> <p>IGRT is the process of two and three-dimensional imaging, during a course of radiotherapy used to direct radiation therapy</p>
IMRT	<p>Intensity Modulated Radiotherapy</p> <p>IMRT is a high precision form of radiotherapy. It conforms the shape and dose of the radiation precisely to the volume of tumour tissue that needs to be treated.</p>
ITV	<p>Internal Target Volume</p> <p>The internal target volume (ITV) is the volume encompassing the CTV, which takes into account the fact that the CTV varies in position, shape and size</p>
PTV	<p>Planning Target Volume</p> <p>The planning target volume (PTV) is a geometric concept, used for treatment planning, and it is defined to select appropriate beam sizes and beam arrangements, to ensure that the prescribed dose is actually delivered to the CTV.</p>
SBRT	<p>Stereotactic Body Radiotherapy</p> <p>Stereotactic body radiotherapy (SBRT) refers to the precise irradiation of an image defined extra cranial lesion associated with the use of high radiation dose in a small number of fractions”.</p>
SRS	<p>Stereotactic radiosurgery</p> <p>Stereotactic Radiosurgery (SRS) is a single fraction, high dose, and stereotactically directed irradiation of a limited volume in the brain or other structures of the skull base</p>
SRT	<p>Stereotactic Radiotherapy</p> <p>Stereotactic Radiotherapy (SRT) is fractionated, high doses, stereotactically directed irradiation of a limited volume in the brain.</p>

Members of the National SBRT NRIG subgroup

NAME	JOB TITLE	ORGANISATION
Peter Kirkbride (Chair)	National Clinical Advisor Radiotherapy Consultant Clinical Oncologist	NHS Improvement Weston Park Hospital, Sheffield
Kate Burton	AHP Consultant Radiographer in Neuro-Oncology	Society & College of Radiographers
Anna Cassoni	Consultant Clinical Oncologist	University College Hospital
Tim Cooper	Associate Director, Radiotherapy	National Cancer Action Team
Kim Cox	Specialised Services Commissioning Manager	Yorkshire and the Humber Specialised Commissioning Group
Cynthia Eccles	Research and Development Radiographer Lead	Oxford Cancer Centre
Carrie Featherstone	Consultant Clinical Oncologist	Beatson Centre Glasgow SRAG
John Fenwick	CRUK Career Development Fellow	Gray Institute for Radiation Oncology and Biology, University of Oxford
Matthew Hatton	Consultant Clinical Oncologist	Weston Park Hospital, Sheffield
Peter Hoskin	Consultant Clinical Oncologist	Mount Vernon Cancer Centre
Steve Kelly	Consultant Clinical Oncologist	Plymouth Hospitals
John Lilley	Clinical Scientist	St James's Institute of Oncology, Leeds
Alexander Martin	Research Fellow	The Harley Street Clinic, London
Liz Miles	National Trials QA Team Co-ordinator	Mount Vernon Hospital
Christopher Nutting	Consultant and Reader in Clinical Oncology	Royal Marsden Hospital and The Institute of Cancer Research
Úna O'Doherty	Senior Clinical Radiotherapy Officer	Health Protection Agency
Tracy Parker	Cancer Policy Team	Department of Health, London
Neil Richmond	Clinical Scientist	Regional Medical Physics Dept, Middlesbrough
David Sherriff	Specialist Registrar in Clinical Oncology	Plymouth Oncology Centre
Bernadette Stack	Radiosurgery Lead Radiotherapist	The Harley Street Clinic, London
Karen Venables	Head of Radiotherapy Physics	Mount Vernon Cancer Centre
Lee Lip Wai	Consultant Clinical Oncologist	The Christie Hospital
Cathy Williams	General Manager	Mount Vernon Cancer Centre