The Shrewsbury and Telford Hospital NHS Trust

BUSINESS CASE REPLACEMENT OF LINEAR ACCELERATOR IN THE RADIOTHERAPY DEPARTMENT

EXECUTIVE SUMMARY

EXECUTIVE LEAD	Dr Saif Awwad, Centre Chief (Oncology)
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STRATEGIC DOMAIN	A. Financial Strength: We will develop and deliver robust services that generate surpluses to reinvest in quality B. Patients, GPs and Commissioners: We will insist that we deliver the best service to our patients, GPs and commissioners C. Quality and Safety: We will always provide the right care for our patients and ensure that they suffer no harm D. Learning and Growth: We will develop our internal processes to sustain our ability to change and improve
ORGANISATIONAL OBJECTIVES	A1. Develop and implement sustainable clinical strategies A2. Develop and grow services which make a positive financial contribution A4. Maximise the productivity and efficiency of our services B2. Ensure our patients have a good experience B8. Engage with GPs to plan and deliver future services B9. Reflect commissioners' plans in our capacity plans and deliver our contractual commitments C3. Provide the right care, right time, right place, right professional C4. Deliver services that offer safe, evidence-based practice C5. Meet regulatory requirements and healthcare standards C6. Ensure our patients suffer no avoidable harm D1. Learn to improve, innovate and cooperate continuously D7. Build service and redesign capacity and capability
INTRODUCTION	The Radiotherapy Department requires two Linear Accelerators in order to meet current demand however the 2100CD is approaching the end of its clinical life (10 years) in June 2012. Using a Linear Accelerator beyond its recommended life cycle is likely to increase downtime, however it should also be noted that this Linear Accelerator is now considered unsuitable for delivering the majority of complex treatments e.g. IMRT, Rapidarc and IGRT which are available at other Centres within our Cancer Network. In addition, the Royal College of Radiologists recommends that the *minimum* equipment required in a cancer centre is **two** linear accelerators. Without this level of equipment waiting times will fall outside nationally agreed levels. If the Royal Shrewsbury Hospital wishes to continue to provide an effective and efficient radiotherapy service to the catchment population, it must continue to retain two fully functional linear accelerators. The risk of service interruption with the reliance on two linear accelerators currently is acceptable, but with one operating beyond its recommended lifecycle puts the service at considerable risk of service disruption and consequently delays in patient care.

	The current Radiotherapy Service demonstrates a need to: ▪ To ensure current radiotherapy capacity is sustained; ▪ To ensure that the existing radiotherapy treatment capacity exists to meet Government targets for waiting times as laid down in the NHS Cancer Plan, the current recommendations of Clinical Governance and best Clinical Practice; ▪ To ensure that the needs of the patient are taken into account in the design and building of the facility ▪ To ensure that alternative treatment facilities are available for the transfer of patients in the event of failure of the linear accelerator; ▪ To ensure the most efficient use of available resources. Historically both Linear Accelerators (2100CD and iX) have generally achieved an average planned availability (uptime) of 99.5%. Over the past year this has now reduced to 98.5%, with individual quarters dipping to 97.0%, suggesting the start of a downward trend and service unavailability. There is increased risk of unreliability as the LA2 (the machine for replacement) goes beyond its working life of 10 years and should the machine fail, the Trust would be unable to deliver capacity to sustain its current workload. In the event of a breakdown, there would be certain patient groups (category 1 Royal College of Radiology guidance) where their clinical outcomes would be affected. Even with short term service failure on one machine, it is not possible to deliver current capacity on one linear accelerator even when introducing extended hours and it would also be undesirable to offer late night appointments to patient and start treatment during late evening. Opportunities for transferring patients to neighbouring Trusts is limited due to geographical restrictions but also due to continuation of care through the consultant teams, furthermore presenting an additional challenges because of the joint conversations required between multi-disciplinary teams. It is important to consider that failure to deliver a radiotherapy service at the Trust would have further implications on the delivery of a Cancer Strategy hence the loss of a radiotherapy service at SaTH may impact on other services in the cancer pathway being fully provided at other Trusts. Given the current treatment capacity and tariff costs per fraction, it costs approximately £5.5k per day when the Linear Accelerator is unavailable for patient treatment due to loss of income and service disruption. Therefore, it can be shown that the cost of each 1% reduction in uptime equates to £12.5k loss to the department. A Major fault on LA2 could easily result in a loss of 8 days (this has occurred at UHNS) or about £45k, over and above the baseline costs above. The Trust will need to have three Linear Accelerators by 2015/16 in order to meet the NRAG guidance targets.
NATIONAL POLICY	The DH publication Improving Outcomes: A Strategy for Cancer (2011) sets out challenges for Cancer Services in England. Over 250,000 people in England are diagnosed with cancer every year and around 130,000 die from the disease. There are approximately 1.8 million people living with a cancer diagnosis and that despite improvements to the quality of cancer services, a significant gap in both survival and mortality rates remains when comparing our services to Europe. In order for England to achieve the European average, then 5,000 lives would be saved every year. If England was to achieve cancer survival rates at the European best, then 10,000 lives would be saved every year. The Improving Outcomes: A Strategy for Cancer sets out objectives in order to improve standards: • Improve access to screening for all groups and introduce new screening programmes where there is evidence they will save lives and are recommended by the UK National Screening Committee; • Achieve earlier diagnosis of cancer, to increase the scope for successful

	treatment – diagnosis of cancer at a later stage is generally agreed to be the single most important reason for the lower survival rates in England; and • Make sure that all patients have access to the best possible treatment. And there are challenges in addition to the delivery of improved survival and mortality rates, in particular: • Many patients live with and beyond cancer for long periods of time, and we need to ensure that everything is done to allow them to live as healthy a life as possible, for as long as possible; • There are variations in patients' experience of care, and we need to make sure that feedback on patient experience informs the design and delivery of services so they reflect what is important to all patients; and • Inequalities in cancer mean that some groups in society have disproportionately poor outcomes.
LOCAL OBJECTIVES	In Shropshire, the population is growing by about 0.6% per year and that demand for radiotherapy is increasing. In order to meet the objectives of the Improving Outcomes: A Strategy for Cancer, healthcare provision in Shropshire must deliver access to the highest quality of cancer treatment and ensure that capacity plans meet requirements to achieve access targets for cancer services. The average number of fractions per linear accelerator in England in 2009/2010 was 6600 (Radiotherapy Data Set Report 2009/2010 DH). The National Radiotherapy Advisory Group (NRAG) 2007 set out on average, services in England should be providing 40,000 fractions per million population by 2010 and up to 54,000 fractions per million by 2016. For Shropshire this suggests 8,300 fractions be delivered on each linear accelerator per year, which has been exceeded since 2011. NRAG's report in 2007 confirmed increased uptake of new technologies was required to ensure best outcomes for patients. One of the technologies it recommended was Proton Beam Therapy (PBT); because of its very precise nature, PBT can avoid damage to critical tissues near the tumour. The strongest clinical case for PBT relates to children and young people with brain tumours. In Shropshire, we are unable to offer PBT, which is not uncommon compared to other Centres. The National Cancer Action Team Cancer Toolkit report highlighted the average machine attendances per linear accelerator over the last 12 months - Shrewsbury was benchmarked nearest to the top. This is achieved in spite of not having a service continuity machine, which many larger departments have. This service continuity machine is not normally staffed but can be used in the event of the breakdown of another machine, or to treat patients during routine maintenance and quality assurance of machines and enable a higher throughput per linear accelerator due to less time lost.
TECHNOLOGICAL ADVANCEMENTS	NRAG 2007 recommended that replacement programmes ensure that linear accelerator are replaced every ten years because after this time, the equipment becomes technically out of date and there is mechanical wear so they are less accurate and less reliable. NRAG recommended that all new and replacement machines are capable of image guided 4D adaptive radiotherapy allowing tumours to be targeted more accurately. The 2100CD (Linear Accelerator being replaced) is now outdated technology with no upgrade path to modern state-of-the-art systems. In addition it is also unable to offer IMRT, an advanced technique which can maximise tumour control whilst significantly reducing associated morbidity and IGRT which can improve treatment accuracy. Both advanced IMRT and IGRT are possible at other local Centres within our Cancer Network. Given that we are unable to upgrade our systems, we are rapidly becoming unable to offer accepted best practice in radical radiotherapy, and therefore risk loss of patients and hence income from SaTH to other Trusts who routinely offer advanced IMRT and IGRT.

SERVICE SUSTAINABILITY	**Intensity Modulated Radiotherapy (IMRT)** National radiotherapy policy (NRAG, 2007) is to provide 4D adaptive radiotherapy (of which IMRT is a vital component) to those patients for whom there would be a benefit. Intensity Modulated Radiotherapy (IMRT) is an advanced type of high-precision radiotherapy that utilises radiation producing equipment, such as Linear Accelerators to deliver precise radiation doses to a malignant tumour. Treatment is planned using CT images to create several intensity modulated beams coming from different directions to produce a tailored dose distribution that maximises the dose to the tumour and prevents damage to adjacent normal tissues. The intensity of the radiation dose can also be varied within the tumour volume, to create complex dose distributions. With IMRT, the ratio of dose received to normal tissues to tumour dose is reduced to a minimum; this may allow higher, and therefore potentially more effective, radiation doses to be safely delivered to tumours with fewer side effects compared with conventional radiotherapy techniques. This now means that 97% of all Linear Accelerators in England have the technical capability and licences to deliver IMRT. Radiotherapy services in England are all at different stages of developing and delivering IMRT. Some have a comprehensive IMRT portfolio and are confident in application of this treatment modality; some have yet to begin. To ensure patients in Shropshire have access to the latest treatment options, the Radiotherapy Department is required to deliver IMRT. The Radiotherapy Department at the Royal Shrewsbury Hospital is in transition to offer IMRT and plans between 24 to 60 patients per year. IMRT is delivered on the 2100iX Linear Accelerator and not on the 2100CD, which is due to be replaced. The latter is currently deemed unsuitable (other than in emergencies) due to its age and low resolution MLC. Without a second IMRT capable Linear Accelerator, the growth in IMRT numbers will be severely restricted over the next 2/3 years. The other IMRT bottlenecks are currently being addressed with additional workstations, more staff in the pipeline and plans to reduce individual verification on the Linear Accelerator, leaving Linear Accelerator capacity as the limiting factor. In addition to the current dynamic IMRT a new Linear Accelerator would also enable Rapidarc IMRT, which is much faster to deliver. This would enable IMRT to be expanded without a follow-on reduction in overall treatment capacity. In the case of Truebeam this goes further since the Linear Accelerator is optimised for efficiency and can deliver FFF Rapidarc which is significantly faster still. It is anticipated by NCAT that about 30% of radical fractions should be delivered using IMRT since this advanced technique can maximise tumour control whilst significantly reducing associated morbidity. This suggests that up to 250 patients per annum should clinically benefit from IMRT. **Image Guided Radiotherapy (IGRT)** NRAG technical development subgroup recommended that four-dimensional (4D) Adaptive Radiotherapy is the future standard of care for radical radiotherapy treatment. 4D radiotherapy takes into account tumour volume in three dimensions and changes with time (4th dimension). Image acquisition during treatment sessions (IGRT) may help to reduce uncertainties about changes in tumour geometry Adaptive therapy allows the treatment set-up and dose delivered to be changed as necessary during a course of treatment. Intensity modulated radiotherapy (IMRT) is likely to be used in conjunction with 4D adaptive radiotherapy. It is expected that this standard of care should be achieved for all departments in England within five to ten years in parallel with the recommended increase in radiotherapy capacity as per National Radiotherapy Advisory Group (NRAG) scenario group recommendation of 2007. The Radiotherapy Department at the Royal Shrewsbury Hospital currently does not have the technology to deliver IGRT on either of our Linear Accelerators. It will only be available if we replace the 2100CD or upgrade the 2100iX Linear Accelerator. This technology would revolutionise the accuracy of our radiotherapy. For simpler treatment kV imaging is vastly superior to current EPI technology. For complex

	(especially including IMRT) radiotherapy cone-beam CT enables visualisation of the set-up accuracy and automatic error correction. SaTH is the only Centre within its network yet to offer this technology, therefore is unable to offer a standard of treatment which is available to patients in other areas and falls behind until the replacement/upgrade takes place. Since IGRT is rapidly becoming accepted best practice in radical radiotherapy, we risk loss of patients and hence income from SaTH to other Trusts who routinely offer IGRT.
RISKS	The Radiotherapy Department requires two Linear Accelerators in order to meet current demand and therefore continual reliance on the 2100CD linear accelerator (LA2) beyond its recommended clinical life (10 years) post June 2012 assumes substantial business risk in relation to reliability: • Inability to meet current standards for treatment delivery as on board imaging is not available at SaTH • Increased rate of breakdown of the Varian Linear Accelerator due to its age and high workloads which will lead to inability to guarantee that all patients will start treatment within national target times; risk of poorer outcomes for patients as number of interruptions that can be compensated for increase due to breakdowns. • Loss of income due to removal of patient groups to neighbouring Trusts where on board imaging is available and capacity is sufficient to ensure national targets are met. • Should the Varian Clinac Linear Accelerator fail the department will no longer comply with minimum equipment standards as stated in Cancer reform strategy, NRAG and peer review measures this will increase the risk of loss of income and patients to other centres. There will also be insufficient capacity to treat all patients referred for radiotherapy within target waiting times. • At a time of national staffing shortages in Radiotherapy and without up to date levels of equipment, SaTH will be unable to compete with other Trusts in the UK to recruit and retain staff. • With reduced access to curative radiotherapy within reasonable travelling times patients will suffer poorer outcomes for their disease. • Increased risk of total loss of radiotherapy service. **Risk of catastrophic failure:** There is the increased possibility that LA2 may fail such that it is either not practical or cost effective to repair. In this case the department would be forced to operate with one Linear Accelerator while a replacement unit was purchased. Given that the lead-in time from placing an order to first patient treatment is a minimum of 10 months, this would leave the service in an impossible situation. The other Linear Accelerator could not meet demand if operated 20 hours per day, which would not in any case be acceptable. Transfer to other radiotherapy centres in the network would be costly (above indicative tariff) and have to take place out of normal hours, for up to 40 patients per day. Purchase from the independent sector would be more costly still and necessitate long patient journeys to Birmingham or further afield. There is no possible acceptable contingency plan that can be made to cover this scenario. **Financial Risks** **Income and Expenditure** ▪ Revenue costs are assumed as per current budget for the replacement machine. ▪ No changes to staffing or other relevant costs. ▪ Capital Charges for preferred option: £301,629 pa, which are broadly in line with existing spend.

The decision not to replace would lead to the Trust not being able to provide a Radiotherapy Service in the longer term. The Current Income and Direct Costs are detailed below.

	Budget 2012/13 £
Income	2,702,000
Direct Costs	
Pay	992,335
Non Pay	1,039,566
Total Direct Costs	2,031,901
Contribution Before Indirect Costs	670,099

The service current provides a £670k contribution towards indirect and fixed costs which the Trust would lose without the Linear Accelerator investment of £2.8m. Therefore the proposed investment would be paid back in revenue terms in circa 4 years.

OPTIONS

1) Do Nothing
2) Install a new **Clinac 21EX** Linear Accelerator @ **£1,622,600** (plus VAT)
3) Install a new **TrueBeam IGRT/SRT** Linear Accelerator @ £**1,867,700** (plus VAT)
4) To **lease** a Linear Accelerator under a 7 year term (10 years is not available):
   (a) Clinac 21EX: 28 payments of £67,491.50 per quarter, total payable £1,889,762
   (b) Truebeam: 28 payments of £78,163.25 per quarter, total payable £2,188,571.

Installation Costs are excluded from the above figures. Varian's tender offer to design, execute and construct the enabling works necessary to install the new linear accelerator within a period of eleven week from commencement of handover of the room is £365,000 (plus VAT**)** in addition a contingency allowance of £32,000 (plus VAT) has been allowed – giving a total of **£397,000** (plus VAT) for installation. This is inclusive of consultancy fees and statutory charges.

In addition the purchase of a water plotting tank (used for commissioning and testing) is required. An ex-demo tank has been sourced at a cost of **£28,234** (plus VAT).

Essential Education Costs

The following costs are essential education costs required for the Radiotherapy and Medical Physic Team. Training is required in 2013/14. Travel costs are excluded.

ED: TrueBeam Technical Maintenance		17,000
ED: TrueBeam Technical Maintenance II		18,000
Tech Maint OBI		7,000
OBI Physics Course		7,000
	Sub-Total	49,000
	VAT	9,800
	Total	**£58,800**

	The Trust's Capital Planning Group has confirmed that an allocation of c£2m is available during this financial year (2011/12) therefore investment would be split over 2 financial years.
PREFERRED OPTION	**Option 3: Truebeam IGRT/SRT Linear Accelerator** This Option enables the Trust to deliver IMRT and provide advanced technology which maximises tumour control and reduces morbidity, together with IGRT which improves treatment accuracy. This enables patients of the SaTH NHS Trust access to technology already available within our Cancer Network. This requires a financial investment of **£2,810,321**, which includes: ▪ Truebeam IGRT/SRT Linear Accelerator at £1,867,700 ▪ Installation & Contingency - £397,000 ▪ Water Plotting Tank £28,234 ▪ Education/Training Costs - £49,000 ▪ VAT at 20%
Recommendations	The Board is asked: • to **SUPPORT** a capital allocation of £2,810,321 for the supply and installation of a replacement linear accelerator, image server and Eclipse workstation, and water plotting tank; • to **ACKNOWLEDGE** that £2,275,121 will be funded out of remaining funds from the 2011/12 programme.