IPEM Institute of Physics and Engineering in Medicine

Submission for Multiple Technology Appraisal of INTRABEAM Photon Radiosurgery System for Adjuvant Treatment of Early Breast Cancer from the Institute of Physics and Engineering in Medicine (IPEM)

Radiotherapy is traditionally delivered in large acute hospitals by a multi-disciplinary professional team composed of Clinical Oncologists, Radiographers and Medical Physics staff. The professional body for medical physicists in the UK is the IPEM who are acting as consultees in this appraisal.

By law, under the Ionising Radiation Medical Exposure Regulations 2000 (IRMER2000), Medical Physics Experts (MPEs) must be closely involved in every therapeutic medical exposure. The MPE must be contracted full-time to the radiation employer and available at all times in Radiotherapy practices[1]. Additionally, under the Ionising Radiation Regulations 1999 (IRR99), hospitals must appoint a Radiation Protection Advisor (RPA) where Ionising Radiations are in use.

Typically physics involvement in radiotherapy includes:

i) advice on procurement;
ii) radiation protection advice and critical examination;
iii) acceptance testing and technical commissioning of equipment;
iv) responsibility for and management of the quality assurance programme;
v) development of standard operating procedures;
vi) routine service support.

Radiotherapy delivery requires a minimum of 2 trained Operators[2] to provide independent verification of treatment parameters. For External Beam Radiotherapy (EBRT) this is traditionally undertaken by therapeutic radiographers with physics support available on site.

The INTRABEAM system represents a paradigm shift in treatment delivery, potentially taking radiotherapy out of the major centres into smaller hospitals with no prior infrastructure for the highly specialist modality of radiotherapy treatment. This represents a benefit for patients who no longer need to travel to specialist radiotherapy centres, but it creates a requirement for new INTRABEAM centres to access the required skill sets for delivery of this service to ensure treatments are delivered accurately and safely.

To date, INTRABEAM has been used clinically in five NHS centres and two private centres in the UK. Most patients have been treated as part of the TARGIT randomised controlled trial, comparing intraoperative radiotherapy using INTRABEAM with conformal EBRT. One of these centres was a District General Hospital supported by the local Cancer Centre. A variety of staffing models have been used within these centres. In all cases a Registered Clinical Scientist (Radiotherapy Physics) was available on site and an MPE contactable throughout treatment. Where treatment was delivered on a non-Radiotherapy site for practicality the Clinical Scientist acted as one of the Operators. The second Operator could be a Physicist, Radiographer or Clinical Technologist. IPEM would advise that this model is maintained in all future centres.

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[1]Medical and Dental Guidance Notes. IPEM, 2002.
[2]IRMER2000. HMSO, 2000.

Independent verification of dosimetry of radiotherapy systems is recognised best practice in the UK following a number of incidents where systematic errors caused by human error in dosimetry were exposed. There is a recognised scheme of external audit for radiotherapy equipment overseen by IPEM. It is recommended that, especially with new technologies such as this, there is an agreed programme of technical commissioning including independent measurement equipment, to ensure consistent, accurate and safe treatment. This will have resource implications.

The typical time frame for delivery of INTRABEAM radiotherapy is ~ 25 – 40 mins, however the multi-professional team needs to be available for longer than this, typically 2- 3 hours per patient.

Issue of guidelines advocating use of INTRABEAM for all eligible breast patients would result in roll out of radiotherapy to a significant number of new centres. These centres would require either local Physics support or a Service Level Agreement with existing radiotherapy providers. Either way this would require an increase in Radiotherapy Physics staff numbers. This professional group appears on the national Shortage Occupation List. Therefore, recruitment and training of this staff group should be factored into the implementation time frame should the technology be approved. The increased time in theatre compared to surgery alone will also impact on theatre capacity requirements.

Consideration should be given in assessment to the comparator model of External Beam Radiotherapy (EBRT). Typically in the UK most patients receive 15 daily fractions of treatment (over three weeks) as opposed to 25 fractions, which were used historically. Current trials (e.g. FAST-Forward) include evaluation of hypo-fractionation with just 5 daily fractions (in 1 week). Increasing uptake of hypo-fractionation will significantly impact on the relative cost benefit.

In comparison with other modern breast trials the Quality Control of the EBRT arm of the TARGIT trial was minimal. From other radiotherapy trials, variation in protocol is known to affect outcome[3]. This may impact on the observed differences between cohort outcomes, e.g. increased toxicity in the EBRT arm.

Other methods of partial breast irradiation are in clinical use around the UK – these include HDR Brachytherapy and External Beam techniques. These are likely to provide an alternative option for these patients and these technologies are already available in a wide number of Cancer Centres.

In conclusion, we believe that this technique could be practically implemented across the UK. However, resource implications will need to be carefully considered, especially the provision of physics expertise to centres with no previous experience of specialist radiotherapy techniques.

David Eaton and Claire Birch
on behalf of IPEM

About IPEM

Physicists, engineers and technologists play vital roles in delivering our healthcare. The Institute of Physics and Engineering in Medicine (IPEM) is the professional organisation that represents this workforce. We are a charity with over 4,000 members from healthcare, academia and industry.

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[3]Ohri et al J Natl Cancer Inst 2013, Fairchild et al Int J Radiat Oncol Biol Phys 2013.

Our members help to ensure that patients are correctly diagnosed and safely treated for illnesses such as cancer and stroke. They also maintain and manage medical equipment such as MRI and ultrasound scanners, X-ray machines, drug delivery systems and patient monitors.
Their research and innovation leads to new technologies and methods that improve on existing medical treatments. They provide new solutions that enable older people and patients with injuries or long-term conditions to complete everyday tasks.

IPEM's objectives are to:

- Ensure and improve the quality, safety and effectiveness of science and technology in healthcare.
- Maintain high standards of professional development for healthcare scientists, engineers and technicians.
- Ensure that the right medical physics and biomedical engineering workforce is in place and provide our members with the support that they need.
- Encourage research and development and increase the uptake of new knowledge and innovations by the medical physics and biomedical engineering sectors.
- Raise the profile of medical physics and biomedical engineering.
- Build two-way engagement with patients and public.
- Ensure and improve the quality, safety and effectiveness of science and technology in healthcare.

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