Horizon Scanning Technology Summary

National Horizon Scanning Centre

Dose Verification System for patients undergoing radiotherapy for breast and prostate cancer

April 2007

This technology summary is based on information available at the time of research and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes.
**Dose Verification System (DVS) for patients undergoing radiotherapy for breast and prostate cancer**

**Target group**
- For patients treated with photon beam radiotherapy (the most common form of external beam radiotherapy) for breast or prostate cancer.

**Technology description**
The Dose Verification System (DVS) is a wireless implantable sensor designed to target tumours and measure radiation dosage *in vivo*. It is intended for use alongside radiotherapy treatment for patients with breast or prostate cancer, improving the precision of radiotherapy and protecting healthy tissue surrounding tumours. If DVS becomes available in the UK, it is likely to be used as an additive or substitute to current surface dosimetry verification.

The DVS consists of an implantable dosimeter for measuring radiation dosages at depth, an insertion tool for implanting the dosimeter and a reader system for receiving dosage measurements. The reader contains software for monitoring daily and cumulative dosage history. DVS uses two MOSFET (metal oxide semiconductor field effect transistor) dosimeters, measuring 2mm by 18mm, which are permanently implanted in the body, and act as a radiation-sensing element. Radiation dosages are communicated telemetrically to the handheld reader system, and using the software, dosages can be reviewed after treatment. The device can be used as a point of reference to facilitate image guided radiotherapy.

**Innovation and/or advantages**
DVS is a new *in vivo* technique that could be used to increase the accuracy of radiotherapy dosing. If DVS becomes available in the UK, increased dose accuracy may improve long-term patient outcomes, safety and quality of life.

**Developer**
Sicel Technologies Inc.

**Place of use**
- Home care e.g. home dialysis
- Secondary care e.g. general, non-specialist hospital
- General public e.g. over the counter
- Community or residential care e.g. district nurses, physio
- Tertiary care e.g. highly specialist services or hospital
- Primary care e.g. used by GPs or practice nurses
- Emergency care e.g. paramedic services, trauma care
- Other:

**Availability, launch or marketing dates, and licensing plans:**
Dose Verification System® (DVS) received FDA approval for use in breast cancer in April 2006. This approval was amended in July 2006 to include prostate cancer.

Sicel Technologies anticipate filing for a CE mark in June/July 2007 and if successful, expect to introduce DVS to the UK in Q1 2008 through a UK distributor.
NHS or Government priority area:

☑ Cancer  □ Cardiovascular disease  □ Children
□ Diabetes  □ Long term neurological conditions  □ Mental health
□ Older people  □ Public health  □ Renal disease
□ Women's health  □ None identified  □ Other:

Relevant guidance
Breast cancer:
- NICE clinical guidelines in progress (due January 2009):
  - Early breast cancer - diagnosis and treatment.
- SIGN clinical guideline. Management of breast cancer in women, 2005\(^1\).
- Improving outcomes in breast cancer. NICE cancer service guidance, 2002\(^2\).

Prostate cancer:
- Prostate cancer: diagnosis and treatment. NICE guideline in progress (due January 2008).
- High dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer. Interventional Procedure Guidance. NICE. 2006\(^3\).
- Improving outcomes in urological cancers. NICE cancer service guidance, September 2002\(^4\).

Clinical need and burden of disease
Breast cancer is the most common cancer for women in England and Wales, with about 38,910 new cases diagnosed\(^5\) and 10,950 deaths\(^6\) recorded each year. Prostate cancer is one of the commonest cancers in men. Each year there are about 28,870 new cases\(^5\) in England and Wales and 9,170 deaths\(^6\).

Radiotherapy is a common treatment option for patients diagnosed with breast or prostate cancer. For women with breast cancer, radiotherapy is given following breast conserving surgery or mastectomy\(^1\). For men with prostate cancer, radiotherapy is used in more advanced cases where prostatectomy is unlikely to or has not achieved complete resection; where prostate specific antigen (PSA) rises indicative of local recurrent or persistent tumour; and in early stage cancer where prostatectomy is contraindicated or is not the patient’s preference.

The number of patients prescribed curative radiotherapy for breast cancer is estimated as 21,646\(^{a,7}\) per year. The number of patients prescribed curative radiotherapy for prostate cancer is estimated as 6,982\(^{a,7}\) per year. If DVS becomes available in the UK it could therefore potentially be used as a dosimeter in approximately 28,630 patients.

Between April 2000 and April 2006 there were approximately 200 reportable radiotherapy incidents where patients received radiation dosages 20% or more higher than intended\(^8\). In a longitudinal study of prostate cancer patients, at 8 years follow-up of patients with a pre-treatment PSA of 10-20 ng/mL, 19% who received the lower radiation dose (<71.5 Gy) had no evidence of disease compared to 84% of patients who had received the higher radiation dose (>75.75 Gy) (p=0.0003)\(^9\).

\(^{a}\) Based on the National Cancer Services Analysis team estimates that 31% of all radiotherapy courses are given to treat breast cancer, 10% are given to treat prostate cancer and the average patient has 1.6 courses of radiotherapy.
Existing comparators and treatments

Skin surface dosimeters can be used at both the entrance and exit sites to provide an extrapolated estimate of the radiation dosage received at the tumour site. Current surface dosimeters verify dosage, acting as a quality assurance of the machine rather than informing calculations used to decide the treatment process.

Efficacy and safety

Two studies of DVS in vitro within an acrylic simulated clinical setting maintained at body temperatures have been published\textsuperscript{10,11}. One published trial of ten patients with unresectable malignant disease (not only breast or prostate malignancies) has assessed the movement of the implanted device\textsuperscript{12}. Trials of DVS are ongoing in conjunction with other treatment devices such as Cyberknife®\textsuperscript{b}.

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Sicel Technologies Inc.</th>
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<tbody>
<tr>
<td>Status</td>
<td>Conference abstract\textsuperscript{13,14}</td>
</tr>
<tr>
<td>Design</td>
<td>Unrandomised, uncontrolled, multicentre</td>
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<tr>
<td>Participants in trial</td>
<td>n=60 (30 with breast cancer, 30 with prostate cancer). 49/60 patients received 2 dosimeters. Some patients received brachytherapy in addition to external beam radiation therapy. Patients were given CT scans every 2 weeks to measure movement of the dosimeters.</td>
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<tr>
<td>Primary outcomes</td>
<td>Degree of movement and adverse events. Comparison of in vivo measured dose to the calculated dose.</td>
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| Key results | 59/60 patients completed radiation therapy: 3 cases of device movement >5mm. Comparing in vivo measured dose to calculated dose for the >1,600 dose measurements:  
  - Breast cancer: 40% had variance >5%; 21% had variance >7%.  
  - Prostate cancer: 36% had variance >5%; 22% had variance >7%.  
  66% of patients had at least 1 sensor that registered variance ≥5% for 25% of the time.  
  31% registered ≥7% variance 25% of the time. |
| Adverse events | No significant adverse events associated with device. |

Estimated cost and cost impact

Sicel Technologies Inc. estimate the cost for the implant kit (containing two devices and insertion tools) to be in the region of $1200 (£610). The reader (including the software) costs $20,000 (£10,118) as a one off capital cost. Additional costs include the procedure to insert the device.

Potential or intended impact – speculative

Patients

- [ ] Reduced morbidity
- [ ] Reduced mortality or increased survival
- [ ] Quicker or more accurate diagnosis
- [ ] Earlier identification of disease
- [ ] Improved quality of life for patients and/or carers
- [ ] Other:

\textsuperscript{b} Cyberknife® is a treatment device consisting of a linear accelerator, a robot and several x-ray cameras.
Services

☐ Increased use e.g. length of stay, out-patient visits
☐ Decreased use e.g. shorter length of stay, reduced referrals
☐ Other:

Costs

☐ Increased unit cost compared to alternative
☐ New costs: devices, software and insertion costs
☐ Increased costs: more patients coming for treatment
☐ Increased costs: capital investment needed
☐ Savings:
☐ Other:

References

7 UK survey of Radiotherapy Equipment 2006, the number of courses of radiotherapy between 1st April 2004 and 31st March 2005, Provided by National Cancer Services Analysis Team.

The National Horizon Scanning Centre is a constituent of the NHS National Institute for Health Research and is managed under contract from the Department of Health's R&D Division.

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