



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application 1319 – Image-guided radiation therapy for cancer treatment delivery

Applicant: Royal Australian and New Zealand College of Radiologists

Date of MSAC consideration: 63rd MSAC Meeting, 1-2 April 2015
62nd MSAC Meeting, 26-28 November 2014

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at www.msac.gov.au

1. Purpose of application and links to other applications

An application requesting MBS listing of image-guided radiation therapy (IGRT) for cancer treatment delivery was received from the Trans-Tasman Radiation Oncology Group (TROG) by the Department of Health in August 2011. As a result of completion of the Assessment of New Radiation Oncology Treatments and Technologies (ANROTAT) project being undertaken by TROG, the Faculty of Radiation Oncology within the Royal Australian and New Zealand College of Radiologists has now assumed responsibility for sponsoring this application.

2. MSAC's advice to the Minister – April 2015 consideration

After considering the available evidence presented in relation to safety, clinical effectiveness and cost-effectiveness of Image Guided Radiation Therapy (IGRT) for the treatment of cancer, MSAC supported public funding of IGRT on a cost neutral the basis relative to MBS expenditure on three-dimensional conformal radiotherapy (3D-CRT).

Summary of consideration and rationale for MSAC's advice

MSAC considered applications requesting MBS listing of intensity modulated radiation therapy (IMRT; application 1182) and image guided radiation therapy (IGRT; application 1319) concurrently.

MSAC reaffirmed that, on balance, there is insufficient evidence of superior outcomes for IGRT compared to portal imaging with off-line post-treatment assessment. MSAC agreed that IGRT should be MBS listed. However, MSAC directed that this listing be cost neutral relative to the comparator.

MSAC noted that IGRT is currently funded under existing items for external beam radiation therapy treatment verification (items #15705 and 15710).

MSAC noted that although the application was not cancer-specific, the bulk of the evidence related to prostate cancer. MSAC found that the evidence:

- supported non-inferiority in relation to acute effects
- was insufficient in relation to late effects
- did not support the safety of dose escalation with IGRT.

MSAC was concerned about the inconsistencies in the evidence of clinical effectiveness. Most of the studies that show a benefit with daily IGRT used simulations for non-IGRT comparisons. MSAC was also concerned that patient outcome benefits were based on expert opinion rather than clinical evidence.

MSAC noted advice from the Department on the outcome of further discussion with the applicant. The revised proposal included:

- one item for IMRT simulation and planning
- one IMRT treatment item
- one IGRT item
- proposed Schedule fees which were calculated by identifying the current utilisation of IG-IMRT and projecting growth in services across the forward estimates. This process recognised that IG-IMRT requires the highest level of complexity in regard to dosimetry and treatment verification.
- a redistribution of that funding in recognition that the most complex and resource intensive component of the service is the dosimetry.

MSAC had previously expressed concern that IGRT was required with every IMRT session compared to off-line post-treatment verification which was thought to be provided daily for the first week and then weekly thereafter. Following MBS data analysis, the Department advised that the utilisation rates for 3D-CRT and IMRT were similar with the average course of curative 3D-CRT treatment in 2013-14 associated with a median of 30 treatment verification scans.

MSAC noted the original economic evaluation was based on a cost minimisation analysis with the following assumptions:

- that verification scans (non-IGRT) were performed daily for the first week, and weekly thereafter
- the verification scan (15705 or 15710) fee used for the calculations was \$76.60
- either verification scan or IGRT (not both) can be claimed for any course of EBRT
- that image guidance is done daily
- the overall cost to the MBS per course of EBRT is identical whether IGRT or verification scans are used

The total cost for listing IGRT on the MBS, based on cost minimisation against verification scans (items 15705 and 15710), is expected to be cost neutral. This is based on the assumption that the frequency of utilisation of IGRT and 3D-CRT treatment verification is similar and that the cost of IGRT will be offset by a reduction in the claims for treatment verification items.

MSAC noted advice on a cost neutral implementation strategy from the Department. Costing was based on 2013-2014 data on patient numbers and expenditure and projection of patient numbers to 2017-2018.

It was also noted that from 1 January 2016 the new Medicare Safety Net will be capped at 150% of the Schedule Fee, which will limit the proportion of out-of-pocket costs that count towards the safety net threshold.

MSAC Review of November 2014 Discussion

At the November 2014 meeting, after considering the strength of the available evidence in relation to safety, clinical effectiveness and cost-effectiveness, MSAC agreed that the evidence did not demonstrate improved health outcomes for IGRT over the comparator of portal imaging with off-line post-treatment assessment. MSAC noted that the meeting had foreshadowed funding of IGRT on a cost neutral basis subject to the provision of Departmental advice on:

- an implementation strategy which achieves budget neutrality such as a bundle fee structure; and
- current utilisation of MBS treatment verification items.

Other key issues from the November 2014 discussion included:

MSAC observed that IGRT is currently funded under existing MBS items for 3D-CRT treatment verification. The applicant is proposing IGRT to replace portal imaging with off-line post-treatment assessment for use with 3D-CRT and IMRT. IGRT is a technique that more closely targets the radiation dose to the tumour, and reduces the dose to surrounding tissue. MSAC noted the applicant's claims that this decreases potential side effects and improves outcomes.

In discussing the evidence, MSAC agreed that the effectiveness outcomes for IGRT were complex and inconsistent across patient populations, cancer types and clinical outcomes. A primary concern was that many studies compared IGRT planning target volume (PTV) margins and tumour dosimetry to simulations of non-IGRT scenarios which assume superiority of IGRT over non-IGRT. MSAC commented that where health outcomes were reported there was no statistically significant difference between IGRT and non-IGRT. Evidence from the ANROTAT study of prostate cancer was considered. However, MSAC considered that the prostate cancer study was too small to permit extrapolation of the effectiveness and utility of IGRT more generally.

MSAC discussed concerns raised by the applicant regarding the interpretation of evidence and the validity of the assessment. However, MSAC considered the quality of the available studies to be poor with inconsistent evidence of safety and clinical effectiveness. Overall, MSAC agreed that the assessment report represented a fair analysis of a poor dataset.

MSAC reiterated that a cost minimisation analysis was appropriate, noting that the analysis had assumed that current practice is for a verification scan to be done once daily for the first week then once per week thereafter. Note that this assumption of how non-IGRT (portal imaging) verification scans are currently used in practice was incorrect, as evidenced by the subsequently available Medicare data.

MSAC's November 2014 consideration

After considering the available evidence in relation to safety, clinical effectiveness and cost-effectiveness, MSAC deferred the application to seek further information from the Department:

- regarding a potential implementation strategy which achieves budget neutrality such as a bundle fee structure; and
- Medicare data regarding current utilisation of MBS items to estimate the number of treatment verifications per treatment course.

MSAC concluded that the evidence overall did not indicate improved health outcomes over the comparator of portal imaging with off-line post-treatment assessment, and so foreshadowed its intention to support funding of IGRT on the basis of an implementation strategy that would achieve budget neutrality, taking into consideration the different frequency of use between IGRT and its comparator.

Summary of consideration and rationale for MSAC's advice

MSAC considered this application alongside MSAC application 1182 for IMRT as it was proposed that IGRT would be used alongside external beam radiation therapy (EBRT), including IMRT.

MSAC noted that IGRT for treatment of cancer is not specifically listed on the MBS but is currently being funded via existing MBS items for radiation therapy treatment verification. The application proposes that IGRT should only be used in conjunction with two radiation therapy technologies, three-dimensional conformal radiation therapy (3DCRT) or intensity modulated radiation therapy (IMRT) to target the radiation dose to the tumour more accurately, thus reducing the dose to surrounding normal tissues (i.e., tighter PTV), thereby decreasing potential side effects associated with the treatment and therefore improving outcomes. It is intended to replace the existing practice of using verification scans following radiation delivery.

MSAC considered the safety and efficacy of IGRT compared to the current standard practice of portal imaging with post-treatment verification and modification to treatment area. For the purposes of the analysis, 42 studies were identified that evaluated the safety and efficacy of IGRT for various cancers. MSAC noted from the nine studies which reported on safety outcomes that there was inconsistent evidence of improved safety with IGRT and insufficient evidence to support safety of IGRT with dose escalation.

MSAC noted that although the application was not cancer specific, the largest evidence base presented for the clinical effectiveness of IGRT was in prostate cancer. MSAC considered that the effectiveness results for IGRT were complex and inconsistent across patient populations, cancer types and clinical outcomes. MSAC was concerned that many of the studies compared IGRT PTV margins and tumour dosimetry to simulations of non-IGRT scenarios which may have incorrectly assumed superiority of IGRT over non-IGRT in every situation. MSAC noted that health outcomes were reported in only a few of the studies. For the studies that did report progression-free survival or relapse free survival there was no statistically significant difference between IGRT and non-IGRT.

MSAC noted the inclusion of additional data from the ANROTAT study. MSAC considered this study of 20 prostate cancer patients was too small to extrapolate the effectiveness and utility of IGRT more generally. In addition, the probabilities of moving between health states

in the Markov model from the ANROTAT study were based on expert opinion only and the health state of surviving prostate cancer (time without symptoms or toxicity [TWiST]) was given a utility of 1.00 which is implausible as it implies perfect health among survivors.

Overall, MSAC considered the quality of the evidence used in the submission to be poor with inconsistent evidence of safety, clinical effectiveness and outcome benefits. In addition the available data are complex with respect to different cancer types, populations, study design and outcomes. MSAC noted that the applicant was unhappy with the contracted assessment report. However, MSAC agreed with ESC that the assessment report generally represented a fair analysis of a poor dataset.

Due to the lack of evidence for any significant benefit in clinical outcomes between IGRT and non-IGRT, MSAC considered that a cost minimisation analysis was appropriate. However, MSAC noted that the economic analysis presented assumed that current practice is for a verification scan to be done once daily for the first week then once per week thereafter. MSAC recalled that it had previously accepted advice in relation to fiducial markers that the currently accepted standard of care was daily verification scans and MSAC received further advice that radiation therapy is moving to daily verification, especially when escalating doses over 70 Gy. MSAC also noted that it is likely that IGRT was being claimed under the current verification item numbers (15705 and 15710), but was unable to quantify the extent of this practice.

MSAC noted that the economic evaluation resulted in a wide range of MBS item fees, between \$22.98 and \$76.60, in order to achieve cost-neutrality; this range depended on the number of fractions of radiation delivered and the frequency of verification per radiotherapy course. MSAC considered the frequency of verification scans and therefore the budgetary impact of publicly funding IGRT, even on a cost minimisation basis, was uncertain.

MSAC requested further advice from the Department regarding a potential implementation strategy which achieves cost neutrality such as a bundle fee structure. MSAC also requested the Department to examine Medicare data regarding the utilisation of existing MBS items for treatment verification practices and provide an estimate on the number of treatment verifications per radiation treatment course.

3. Background

MSAC has not previously considered IGRT for use in cancer treatment.

This application was considered by ESC in June 2014. Following discussion with the applicant additional analysis was commissioned to revise the assessment report following publication of new evidence

4. Prerequisites to implementation of any funding advice

Equipment that could be used to provide the proposed new service was originally identified by the applicant as example listings, all are TGA approved.

Expert advice indicated that a range of other vendors may also offer products/equipment in relation to the service. It is considered that 83.2% of linear accelerators (“linacs”) currently in use in Australia are capable of online image-guided correction (RANZCR 2013).

5. Proposal for public funding

Two proposed MBS item descriptors for IGRT were set out in the Final Protocol. However, the applicant subsequently advised that there was no need to distinguish between planar and volumetric IGRT.

Proposed MBS item descriptor for image guided radiation therapy (online)

MBS XXXXX

Planar/Volumetric Image Guided Radiation Therapy for IMRT - the use of at least two (2) planar image views/projections or one (1) volumetric image set to facilitate a three dimensional adjustment to radiation treatment field positioning, where the following conditions are met;

1. Treatment technique is classified as IMRT
2. Margins applied to volumes (CTV/PTV) are tailored or reduced to minimise treatment related exposure of healthy/normal tissues
3. Decisions using acquired images are based on action algorithms and are enacted immediately prior to or during treatment delivery by qualified and trained staff considering complex competing factors and using software driven modelling programs.
4. Radiation Field positioning requires accuracy levels of less than 5mm (curative cases) or up to 10mm (palliative cases) to ensure accurate dose delivery to the target.
5. Image decisions and actions are documented in the patient's record.
6. The Radiation Oncologist is responsible for supervising the process including specifying the type and frequency of the imaging, the tolerance and action levels to be incorporated in the process, reviewing the trend analysis(es) +/- reports and relevant images during the treatment course and specifying action protocols as required.
7. Where required, re-planning is required when the treatment adjustments are inadequate to satisfy treatment protocol requirements.
8. Imaging infrastructure (hardware and software) is linked to the treatment unit and networked to an image database enabling both on-line and off-line reviews.

Fee: Under development

IGRT is the process of frequent two and three-dimensional imaging that is captured as close as possible to the time of treatment or concurrent with treatment delivery. The images enable the patient or beam position to be corrected before or during treatment delivery. IGRT is used when there is complex dosimetry and in situations where it may be difficult to reproduce the patient position.

IGRT may be delivered using a range of technology:

- two-dimensional imaging localises the target by matching planar kilovoltage (kV) radiographs, fluoroscopy or megavoltage (MV) images with digital reconstructed radiographs (DRRs) from the planning CT.
- three-dimensional imaging which localises the target by comparing a cone-beam computed tomography (CBCT) dataset with the planning computed tomography (CT) dataset from planning.
- ultrasound for image guidance which allows automated scanning from outside of the treatment room.

MRI guided IGRT which provides real-time image guidance is a further option.

6. Summary of Public Consultation Feedback/Consumer Issues

Consumers considered that the proposed intervention could lead to higher costs for the community, specifically in staffing and capital costs. Consumers may reasonably assume the latest treatments are the best treatments. As a lack of information on radiation exposure and

side effect management makes it difficult to assess safety and wellbeing impacts, consumers depend on clinicians to provide evidence-based advice on treatment.

The Protocol Advisory Sub-Committee (PASC) received one response to the public consultation request from a professional body (the Royal Australian and New Zealand College of Radiologists) and six responses from the public.

Overall, feedback on the proposal was positive and did not identify disadvantages. Feedback indicated that the likely usage of such imaging might increase, and it is conceivable that, for some complex cases, such imaging will be used in each treatment session.

Public consultation feedback generally supported the view that IGRT could enable more accurate treatment for the patient and improve patient outcomes. Feedback also supported the applicant's proposal to separate item numbers for multiple planar imaging and volumetric imaging. However, it was suggested that separate fees should be determined because of the fundamental differences between the two.

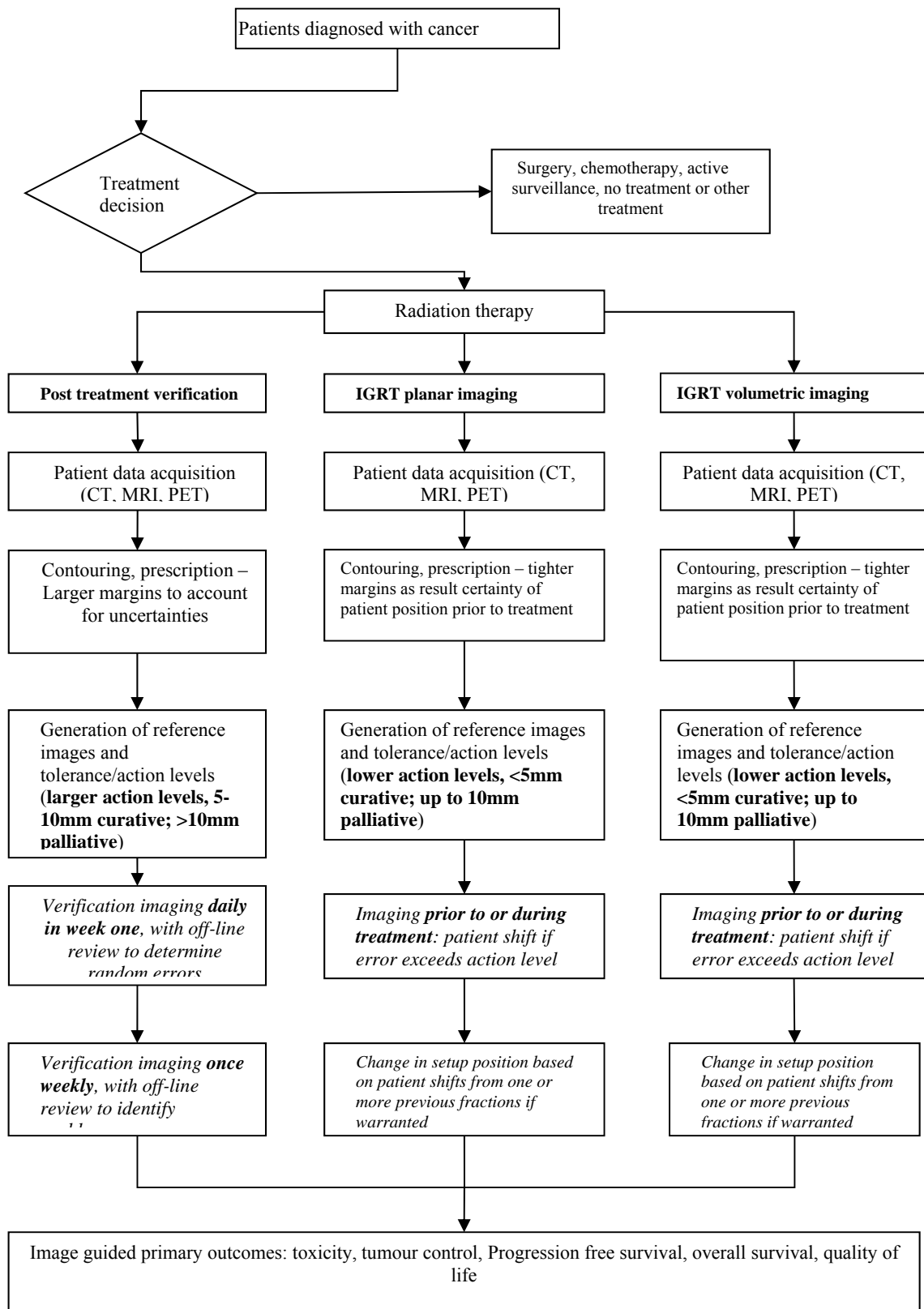
7. Proposed intervention's place in clinical management

IGRT is a process that enables images to be captured immediately before or during the delivery of external beam radiation therapy (EBRT). It is used to adjust patient position to maximise dose to target volumes and improve accuracy of the radiation therapy. This has the aim of increasing the dose of radiation delivered to the tumour, whilst reducing the dose of radiation delivered to normal tissue around the tumour.

The IGRT processes proposed in this application involve multi-plane image sets or volumetric data sets being obtained at the planning stages and again during treatment delivery. Analysis, interpretation and treatment alignment can be adjusted during treatment and in accordance with narrower margins, where appropriate. Review and assessment of the images enables trained staff (using specialised software) to make adjustments to the patient or machine positional parameters, ensuring the radiation is precisely focussed on the tumour. It is claimed that this maximises the prescribed and delivered dose to the target and minimises radiation from EBRT to normal tissues close to the target, providing the opportunity to gain maximum tumour control and decrease possible side effects associated with the treatment.

IGRT is indicated for the treatment of a range of cancers, including (but not limited to) head and neck, prostate, bladder and lung cancers. IGRT is currently funded under existing MBS items for treatment verification. The application proposes that IGRT should only be used in conjunction with 3DCRT or IMRT and is intended to replace the existing practice of using verification scans (currently claimed under MBS items 15705 or 15710) after radiation delivery.

Figure 1 below shows the clinical management algorithm for the proposed new intervention:



8. Comparator

The comparator is portal imaging with off-line post-treatment assessment which is currently claimed under MBS items for treatment verification (15700, 15705 and 15710). This process may use:

- x-rays (portal imaging, megavoltage or kilovoltage, using a linac);
- computed tomography; or
- ultrasound (images captured in at least three dimensions);

In addition, there must be a record of the assessment(s) and any correction(s) of significant treatment delivery inaccuracies detected.

9. Comparative safety

Nine studies reported patient safety outcomes. Seven of the nine studies reporting safety were for prostate cancer and a single study on each for early stage Hodgkin's lymphoma and head & neck cancer.

There was conflicting evidence for safety in prostate cancer, but the majority of studies suggest IGRT leads to a reduction in rectal and bladder toxicities in the treatment of prostate cancer compared to no IGRT, and a reduction in oesophagitis in head and neck cancers.

Seven studies reported on the comparative safety of IGRT versus no IGRT in the treatment of *prostate cancer*. The IGRT methods used and the comparators in each of the studies varied. The most common adverse events reported were rectal/gastrointestinal and bladder/genitourinary.

With respect to rectal/gastrointestinal adverse events, three of the studies reported statistically significant reductions of such events amongst patients treated with IGRT compared with no image guidance; two reported no differences; and the remaining study reported worse acute rectal toxicity amongst patients treated with IGRT compared with no IGRT.

For bladder/genitourinary toxicities, five studies reported these events. Statistically significant reductions in bladder/genitourinary toxicities were reported in four studies; no difference in one study; and one study reported worse acute bladder toxicity amongst patients treated with IGRT compared with no IGRT.

The results reported across the studies are not consistent, however the majority do suggest better rectal and bladder safety profiles for IGRT when used in the treatment of prostate cancer versus no IGRT.

One study reported comparative safety of IGRT and no IGRT in *early stage Hodgkin's lymphoma*. The incidence of grade 2 adverse events in patients treated with 3D-CRT was statistically significantly greater than those treated with IGRT (Pearson $\chi^2=4.09$, $P=0.043$).

One study reported comparative safety of IGRT and no IGRT in the treatment of *head & neck cancers*. The results from this study indicated a statistically significant reduction in the rate of oesophagitis (RR=1.6, $p=0.34$) with the use of image guidance, however no differences were observed for the other reported adverse event outcomes of oral mucositis, dysphagia or xerostomia.

10. Comparative effectiveness

Ten studies reported systematic and random errors of IGRT compared to no IGRT; 21 studies reported the margins used in converting clinical target volume (CTV) to planning target volume (PTV) with IGRT; seven studies reported the dose to tumour in IGRT compared to no IGRT; 16 studies reported dose to normal tissue in IGRT compared to no IGRT; and five studies reported patient clinical outcomes.

Systematic and random errors

Irrespective of cancer type, the consensus was that IGRT will reduce systematic error associated with radiation therapy, and all studies but two (both of which reported no difference), reported a reduction in random error (one study did not report on random errors). However, the magnitude of error, as well as the reduction in error, varied across studies.

Clinical target volume (CTV) to PTV

Results from the studies consistently indicated that smaller PTV margins resulted when daily IGRT was employed, compared with no daily IGRT in the treatment of cancer, although the magnitude of the margins and changes to those margins varied markedly between studies. Most studies compared IGRT volumes to non-IGRT *simulations*.

One study reported that a very large proportion of fractions would have been outside the 5mm (69%) and 3mm (93%) margins in the absence of daily IGRT, although another study did not report any statistically significant differences in the number of unsuccessful fractions between IGRT and no IGRT (defined as the CTV coverage by the 95% isodose line being <99%).

Dose to Tumour

One study did not report statistical significance, but based on the results presented, there is likely no difference in the dose delivered to tumour in rectal cancer between IGRT and no IGRT.

One *prostate cancer* study reported that a statistically significantly higher minimal radiation dose was delivered to 100% of the prostate target, whereas a lower dose was delivered to 95% of the pelvic node, and a reduced maximum dose that covered 2cm³ of the pelvic node target in the IGRT compared with the no IGRT group.

The other prostate cancer study reported that a statistically significantly higher minimal radiation dose was delivered to 95% of the prostate target. It should be highlighted that these prostate studies are of very different design – one comparing two cohorts of patients and the other comparing results from actual IGRT dose delivery to simulated non-IGRT plans. This may aid in explain the discrepancy in the results.

A *head and neck cancer* study reported lower doses delivered to the tumour based on 95% of dose delivered to gross tumour volume and 95% clinical target volume prescribed to 60Gy, though no statistical significance was reported. One of the *lung cancer* studies reported a range of uniformity measures for dosage delivered but the results were inconsistent (there was a statistically significant difference in homogeneity index but not in conformity index) whilst the other reported statistically significantly higher minimum and maximum doses to the tumour. The head & neck and lung cancer studies used non-IGRT simulations as the comparator.

Dose to normal tissue

The majority of studies seem to conclude that IGRT delivers lower radiation to normal tissues and organs at risk in the treatment of cancer, though some fail to reach statistical significance (e.g. small bowel exposure in a prostate study, bladder exposure in a prostate study, mandibular dose in a head and neck cancer study). The magnitude of reduction varies across studies and is likely to be due to the differences in study methods and patients enrolled.

Impact on health outcomes

Two of three *prostate cancer* studies indicated statistically significant improvements in freedom from biochemical failure rates among those treated with IGRT compared with no IGRT, whilst the other reported no statistically significant differences ($p=0.386$) in the 3 year actuarial biochemical progression free survival between treatment without (86.0%) and with IGRT (90.3%).

A *head and neck cancer* study reported no differences between IGRT and no IGRT for three-year loco-regional control or overall survival.

One study reported 3 year relapse-free survival rates for patients with *Hodgkin's lymphoma* treated without ($n=49$) compared to patients treated with IGRT ($n=41$). The 3 year relapse-free survival rate for patients treated with 3D-CRT was 97.8%, and for patients treated with IGRT it was 100%, with the difference not being statistically significant ($p = 0.389$). Two cases of relapse were reported, with one in the 3D-CRT treatment group at 16 months, and one in the IGRT treatment group at 36 months. The Assessment Group noted that this appears to not have affected the relapse free survival rate, possibly because relapse was outside of field treated by RT.

11. Economic evaluation

A cost minimisation approach against existing verification was adopted due to insufficient evidence of improved clinical outcomes between IGRT and non-IGRT. The cost minimisation analysis was based on the following assumptions:

- Current practice is that a verification scan is done once daily for the first week (5 fractions) then once per week thereafter (as specified in the final protocol).
- The fee for verification is \$76.60 per scan, based on MBS item 15705 and 15710.
- Either verification or IGRT imaging, but not both, may be claimed for each course of radiation therapy.
- IGRT scans are done daily, and real time IGRT will attract the same MBS fee as daily imaging.
- The overall cost to the MBS per course of treatment, based on MBS item fees paid, will be the same in both IGRT scenarios and the current situation with verification only.

Based on the above assumptions, the MBS fee per scan may range between \$22.98 and \$76.60, depending on the duration of treatment using IGRT, when cost minimised against

verification scans only.

⊕ **Table 40: Cost minimisation of IGRT against current practice of verification scans only**

Duration of treatment (weeks(fractions)) ¹	Number of verification scans	Cost to MBS(\$)	Number of IGRT daily scans ²	MBS fee per IGRT daily scan ³
1 (5)	5	383.00	5	76.60
2 (10)	6	459.60	10	45.96
3 (15)	7	536.20	15	35.75
4 (20)	8	612.80	20	30.64
5 (25)	9	689.40	25	27.58
6 (30)	10	766.00	30	25.53
7 (35)	11	842.60	35	24.07
8 (40)	12	919.20	40	22.98

¹ Assume that treatment only done during weekdays and 5 fractions per week is delivered

² Assume that scans are done daily and that fee for real time IGRT is the same for daily imaging

³ Assume that only one fee is paid per day of IGRT imaging in lieu of verification

The wide range of values for the MBS fee is due to uncertainty around how often verification is currently being used in clinical practice. If the frequency of use of verification is different to these assumptions, then the cost of the estimated MBS fee for IGRT would also be different. If the frequency of use of verification is greater than the assumption, then cost minimisation would result in a higher fee for IGRT items, and vice versa.

12. Financial/budgetary impacts

The total cost for listing IGRT on the MBS, based on cost minimisation against verification scans (MBS items 15705 and 15710), is not expected to exceed \$32 million.

13. Key issues from ESC for MSAC

ESC considered that the assessment generally represented a good analysis of a poor dataset.

In considering the ANROTAT study, ESC noted that the conclusions from the study were heavily reliant on expert opinion from TROG (such as in the determination of transition probabilities and quality of life of various health states).

ESC noted that evidence regarding patient outcomes was limited to expert medical opinion, not research evidence. ESC was concerned there may be no survival or quality of life benefit from IGRT. ESC noted there is no clearly defined ‘gold standard’ for measuring accuracy in existing radiation therapy.

ESC noted that the economic modelling was presented as a cost-neutral proposal because of insufficient evidence for improved clinical outcomes between IGRT and non-IGRT. Cost neutrality will depend on the assumptions made when developing the cost minimisation approach to the MBS fee and direct substitution for existing verification scans. ESC considered that the validity of these assumptions will be difficult to evaluate.

ESC noted that the current use of verification scans is highly uncertain. On the basis of the economic analysis and the applicant’s assertion that IGRT is currently being claimed under image verification items, ESC was concerned that current practice may be over-reimbursed.

ESC noted that there was no justification for having separate item descriptors for planar IGRT and volumetric IGRT.

ESC noted that the proposed descriptor is for IGRT in conjunction with either 3DCRT or IMRT. IMRT is the topic of a separate MSAC application (1182) from the same applicant.

ESC noted that, in order to be cost neutral, the appropriate MBS fee was highly dependent on the number of verification scans provided.

14. Other significant factors

Nil

15. Applicant's comments on MSAC's Public Summary Document

The Faculty of Radiation Oncology (FRO) commends the MSAC for the development of an MBS item number for IGRT, which is an integral part of safe and accurate delivery of radiation therapy – to ensure there is not geographical miss of the tumour with highly conformal treatment techniques including IMRT. IGRT allows for the radiation to be accurately directed to the cancer while accounting for the movement of organs or tumours within the patient. IGRT will replace existing verification imaging techniques where IMRT is used, but existing verification imaging descriptors need to remain available for use with non-IMRT treatments. The purpose of this application is to ensure that IGRT is available, accessible and reimbursed where clinically indicated.

The FRO disagrees with the assessment's interpretation of the studies on the safety of IGRT. We wish to reiterate that the studies consistently show no worse toxicity or negative impact with IGRT, with all but one showing benefit with IGRT and one showing no impact.

16. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website at: www.msac.gov.au.