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The development of accurate and high quality radiotherapy treatment delivery.

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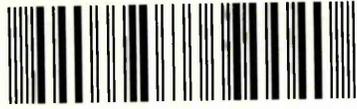
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**THE DEVELOPMENT OF ACCURATE AND HIGH QUALITY
RADIOTHERAPY TREATMENT DELIVERY**

Susan Elizabeth Griffiths

**Published works submitted in partial fulfilment of the requirements of
Sheffield Hallam University for the degree of Doctor of Philosophy on the
basis of published work**

**Submitted research was carried out at Leeds Teaching Hospitals NHS
Trust**

October 2010

Declaration

I, Sue Griffiths, hereby declare that this submission is my own work and that it contains no work published or written by another person except where acknowledged in the text. Nor does it contain material that has been accepted for another degree at this or any other university.

Much of the work submitted here was co-authored. Co-authors of seminal work are aware of, and supportive of, the work being included in this submission.

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I am extremely grateful for the support given and contribution to the research achievements by the Leeds Medical Physics team, particularly for engineering work, and for the collaboration of radiographer colleagues at Leeds and elsewhere. I am grateful also to Clinical Oncologists Dr D.V. Ash, the late Dr G.H. Berry, Dr W.G. Jones, Dr H.J. Close, and Professor C.A. Joslin for allowing their patients to be studied, and for the opportunity to liaise closely with them, also to Dr R. Pearcey, Dr G. Khoury for their help and collaboration in the Leeds accuracy studies. Dr Ash, Dr Jones and Professor Joslin also introduced me to National group work, and both encouraged and supported me in researching and publishing (as also did the late Dr A.J. Ward). Grateful thanks are due to other co-authors, particularly for the help of my clinical colleagues, Chris Short, who co-authored a book, a paper and collaborated in RCR survey work, and Suzanne Stanley for collaboration and support in various studies. Thanks are also due to the Leeds Teaching Hospital NHS Trust and management teams at the former Cookridge Hospital, the location where research was undertaken (now the St James's Institute of Clinical Oncology), to my supervisors (Professor Andy Beavis, Dr Viv Cosgrove, Dr Ann Henry, Mrs Denyse Hodgson and Dr Stephen May), who have advised on the presentation of material for and connected with this thesis, and to my husband Professor John Griffiths for his support during all the work and the writing of this thesis.

The development of accurate and high quality radiotherapy treatment delivery

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Abbreviations and symbols

Treatment fraction

ACORRN Academic Clinical Oncology and Radiobiology Research Network

BTE Basic Treatment Equivalent (formula)

BIR British Institute of Radiology

CC Caudo-cephalic

COIN Clinical Oncology Information Network

CRUK Cancer Research United Kingdom

COR College of Radiographers

CBCT Cone beam CT

CFRT Conformal radiotherapy treatment

CPD continuing professional education

CHART Continuous hyper-fractionated radiotherapy CHART trial

DRR Digitally reconstructed radiograph

DOH Department of Health

HAC (treatment isocentre) height above couch

ESTRO European Society for Therapeutic Radiology and Oncology.

FSD Focus skin distance

ICRU International Commission on Radiation Units and Measurements

IEC International Electro-technical Commission

IGRT Image guided radiotherapy

IPEM Institute of Physical Sciences and Engineering in Medicine

IMRT intensity modulated radiotherapy

Linac Linear accelerator (clinical treatment machine)

MRC Medical Research Council

MRI magnetic resonance imaging

NRAG National Radiotherapy Advisory Group

MLC multi-leaf collimators

PA Postero-antero

PI portal imaging

QA Quality assurance

RCR Royal College of Radiologists

RHA Regional Health Authority

RMH Royal Marsden Hospital

RT01 (The first) MRC radiotherapy prostate trial

RTIG (The RT01) Radiographer Trial Implementation Group

SCF supra clavicular fossa

SHU Sheffield Hallam University

SSD source to skin distance

START Standardisation of Breast Radiotherapy Trial

WTE whole time equivalent (staff)

WHO World Health Organisation

ABSTRACT

Accurate radiotherapy delivery is required for curing cancer. Historical radiotherapy accuracy studies at Leeds (1983-1991) are discussed in context of when radiographers were not involved in practice design. The seminal research was unique in being led by a radiographer practitioner, and in prospectively studying the accuracy of different techniques within one department. The variability of alignment of treatment beams with marks painted on a patient's skin varied daily, and, using film I showed that the alignment of treatment on anatomy varied. I then led 6 sequential studies with collaborating oncologists. Unique outcomes were in identifying the origins of treatment inaccuracies, implementing and evidencing changes in multi-disciplinary practice, thus improving accuracy and reproducibility generally and achieving accuracy for the pelvis to within current norms. Innovations included –

- discontinuation of painted skin marks and developing whole-body patient positioning using lasers, tattoos, and standardised supports
- unification of set-up conditions through planning and treatment
- planning normal tissue margins round target tissue to allow for inaccuracies (1985)
- improved manual shielding methods, changed equipment usage, its quality assurance and design
- influenced the development of portal imaging and image analysis

Consequences and current implications

The research, still cited internationally, contributed to clinical management of lymphoma, and critically underpins contemporary practice. It led to my becoming the first radiographer invited into multi-disciplinary collaborative work, to advise in the first multi-centre clinical trials to consider treatment delivery accuracy, contribute to books written from within other disciplines and inform guidelines for good practice so helping to improve practices, with recent publications. I thus led my profession into research activity. Later work included development of a national staffing formula for radiotherapy Centres, and contributing to the evidence-base for improved National radiotherapy resourcing. I recently researched and developed a textbook (second edition) on quality in treatment delivery.

List of publications submitted

Ref No	Details of the Published Work (<i>n.b. 'radiographer' in notes refers to therapy radiographer</i>)
	Radiotherapy accuracy studies
1	Griffiths SE, Pearcey RG (1985) The reproducibility of large lead protected radiotherapy fields to the abdomen and pelvis. <i>Radiography</i> 51: 247-250 (<i>First radiographer led research-seminal work on reproducibility related to set-up technique, and first radiographer authored paper</i>)
2	Pearcey RG, Griffiths SE (1985) The impact of treatment errors on post operative radiotherapy for testicular tumours. <i>British Journal of Radiology</i> 58: 1003-1005
3	Griffiths SE, Pearcey RG (1986) The daily reproducibility of large complex-shaped radiotherapy fields to the thorax and neck. <i>Clinical Radiology</i> 37: 39-41
4	Pearcey RG, Griffiths SE (1986) An investigation into the daily reproducibility of patient positioning for mantle treatments. <i>Clinical Radiology</i> 37: 43-45
5	Griffiths SE, Pearcey RG, Thorogood J (1987) Quality control in radiotherapy: the reduction of field placement errors. <i>International Journal of Radiation Oncology, Biology, Physics</i> 13: 1583-1588 (<i>The first study to report improved accuracy from described changes in set-up methods, recently referenced internationally and by the American Association of Physicists in Medicine</i>)
6	Griffiths SE, Khoury GG, Eddy A (1991) Quality control in radiotherapy during pelvic irradiation. <i>Radiotherapy and Oncology</i> 20: 203-206 (<i>European award won for this work, continues to be referenced internationally</i>)
7	Griffiths S, Stanley S, Sydes M, and RT01 Radiographers Group on behalf of Collaborators (2005) Recommendations on best practice for radiographer set-up of conformal radiotherapy treatment for patients with prostate cancer: experience developed during the MRC RT01 trial (ISRCTN 47772397) <i>J Radiotherapy in Practice</i> 4 issue 2 (<i>First radiographer led MRC article, and first article on detailed radiographer practice based on accuracy analysis from repetitive imaging in a multi-centre trial</i>).
8	Stanley S, Griffiths S, Sydes MR, Moore R, Syndikus I, Dearnaley DP and RT01 Radiographers Group on behalf of RT01 Collaborators (2008) Accuracy and reproducibility of Conformal Radiotherapy using data from a randomised controlled trial of conformal radiotherapy in prostate cancer (MRC RT01, ISRCTN47772397). <i>Clin Oncol</i> 20:582-590 (<i>First article with overall accuracy results and evidence-based imaging conclusions from a multi-centre trial</i>)
	Publications related to, and as a result of the impact of, studies 1-6
9	Griffiths SE (1986) Reproducibility in radiotherapy. <i>Radiography</i> 52: 167-169 (<i>Education article</i>)
10	Griffiths SE (1989) Hit or Miss - is perfection achievable in radiotherapy? <i>Radiography</i> 55: 24-26 (<i>Cited in a review of development of treatment imaging by an international expert, and by a physiotherapist preparing RT patients</i>)
11	Griffiths SE (1990) Radiotherapy quality control: portal and verification films. <i>Radiography</i> 56: 17 (<i>Education article first article giving information on methods of use of these films, referenced in a review of the development of treatment imaging by an international expert</i>)
12	Griffiths SE (1997) Section 2.2 The radiographers view. In: The design of radiotherapy treatment room facilities. Eds Stedeford B, Morgan H M, Mayles W P M (IPEM Report 75): The Institute of Physics and Engineering in Medicine. (<i>The only radiographer to input</i>)

13	Flynn A, Griffiths SE, Joslin CAJ (2001) Chapter 6 Safe Practice and Prevention of accidents in afterloading. In: Safe practice and prevention of accidents in afterloading brachytherapy Eds Flynn A, Hall E J, Joslin CAJ Arnold (<i>The only radiographer to input</i>)
14	Griffiths SE as group member (1999) Writer/lead- Section 3 Treatment Delivery, also Appendix 4 Reproducibility in Treatment Delivery. In: Guidelines for external beam radiotherapy. RCR Radiotherapy Clinical Oncology Information Network. Clinical Oncology 11: S148-S171 (<i>First radiotherapy clinical process guidelines</i>)
15	Trial Management Group - member (1999) Standardisation of Breast Radiotherapy (START) Trial. Clinical Oncology 11: 145-147. (<i>First radiotherapy trial to have a radiographer involved from the outset including on the QA group</i>)
16	Sydes MR, Stephens RJ, Moore AR, Aird EGA, Bidmead AM, Fallowfield LJ, Graham J, Griffiths S, etc. on behalf of collaborators. (2004) Implementing the UK MRC RT01 trial (ISRCTN 47772397): Methods and practicalities of a randomised controlled trial of conformal radiotherapy in men with localised prostate cancer. Radiother Oncol 72: 199-213 (<i>First trial specifying accuracy tolerance and monitoring by treatment imaging, and a radiographer QA group</i>)
17	Mayles WPM, Moore AR, Aird EGA, Bidmead AM, Dearnaley DP, Griffiths SE, Stephens RJ, Warrington AP on behalf of all the RT01 contributors (2004) Questionnaire based quality assurance for the RT01 trial of dose escalation in conformal radiotherapy for prostate cancer (MRC - ISRCTN 47772397). Radiother Oncol 73:199-207 (<i>First QA process document to include extensive details of treatment set-up practice</i>)
	Publications on wider quality issues arising from accuracy studies and related developments
18	Probst H, Griffiths SE (1995) Increasing the work-speed of radiographers: the effect on the accuracy of a set-up of a complex-shaped cranial field, part of a matched cranio-spinal junction. Radiotherapy and Oncology 38:241-245
19	Short CA, Griffiths SE (1996) Radiotherapy: Developments, contradictions and dilemmas. Invited Review article. Radiography 2: 177-189. (<i>New journal</i>)
20	Griffiths S (1999) Therapy Radiographer Staffing for the treatment and care of cancer patients. Guest Editorial. Journal of Radiotherapy in Practice. Vol 1 issue 4 p 159-232 (<i>New Journal</i>)
21	Griffiths S, Delaney G, Jalaludin B (2003) An assessment of Basic Treatment Equivalent at Cookridge Hospital. Clinical Oncology 14:399-405 (<i>By email with Australian experts</i>)
22	Probst H, Griffiths S (2006) Moving to a High-tech Approach to the Irradiation of Early Breast Cancer: Is it possible to Balance Efficacy, Morbidity and Resource Use? Clinical Oncology 18: 268-275
23	Griffiths S, Craig C, Abraham M (2006) Radiographer roles and risk management in Radiotherapy. Journal of Radiotherapy in Practice. 5, 137-146 (<i>Work underpinning the first radiographer staffing guidelines since the 1970s</i>)
	Text book incorporating all quality findings
24	Griffiths SE (2008) Radiotherapy: Principles to practice. A practical manual for quality in treatment delivery. Second Edition. University of Leeds print services © Leeds Teaching Hospitals NHS Trust. ISBN 978-0-9553256-1-8 (<i>Unique in content/subject areas. First Edition by S Griffiths and C Short, Churchill Livingstone, Longman UK, 1994</i>)

CHAPTER 1. INTRODUCTION TO THE RESEARCH WORK AND ITS SIGNIFICANCE

1.1 The need for accuracy in radiotherapy

Around 60% of cancer patients are treated curatively by high doses of radiation, directed at tumour tissue. Radiotherapy makes a significant contribution to cure in 40% of long term survivors (NRAG 2007). Its success relies on accurate delivery of the radiation dose within the prescribed timeframe. It is crucial that all target tissue receives the intended dose on each replicated treatment fraction and that tissues such as the spinal cord are protected, as treatment doses result in cell death.

To achieve the highest cure rate with lowest possible morbidity, an accurate high quality radiotherapy process is required, involving many related factors. The tumour is staged and, currently, localized in three dimensions (formerly in two) relative to the body surface and treatment planned using appropriate images. Methods of treatment planning to predict radiation dosimetry in the patient to $\pm 5\%$ accuracy are required. Many factors throughout the planning and preparation process influence the accuracy of treatment delivery. Details of methods vary between radiotherapy Departments and with treatment site and technique. A reproducible treatment position, tolerable to the patient and effective for technical processes, is required, with skilful set-up methods proven to ensure treatment is accurate each day to within a few millimetres. All methods rely on the use of marks or tattoos on the skin or a closely fitting plastic shell, for positioning treatment beams aimed at tissues at various depths within the patient. Because of the mobile nature of the body and dynamic motion of many tissues, the process presents a complex four dimensional challenge. Patient ability to comply with positioning requirements influences achievable accuracy.

The quality of radiotherapy delivery depends also on available equipment and staff numbers, and the skills and knowledge of professional staff involved. Radiographers are involved in treatment planning, assessing, preparing, positioning the patient and setting them up for each procedure. They autonomously deliver treatment, using set-up checks to optimise accuracy,

undertaking PI verification against treatment planning images with decisions and actions, and monitoring the patient and radiation dose throughout.

For some cancers, a higher dose increases the chance of cure, but tissue tolerance limits necessitate reducing the high-dose volume. Sometimes, fewer high dose fractions are used. Complex technology and newer techniques have evolved, allowing smaller, complex-shaped volumes to be localised and treated, with very steep dose gradients within the target volume/s. Small volumes receiving an even higher 'boost dose' are superimposed on a larger volume, and/or adjacent target volumes are matched to each other. Chemotherapy, given concomitantly for many conditions, enhances the effect of radiation on tissue. The need to achieve high quality is even greater with these higher risk approaches with increased potential for increased cure rates and decreased long-term morbidity.

1.2 Effect of accuracy and technique on treatment outcome and morbidity

Technical efficacy in treatment delivery influences treatment outcome.

Hodgkins' disease relapse rates following mantle treatment increased (from 14% to 54%) and in field and marginal relapse rates increased (from 7% to 33%) where port films were retrospectively judged 'inadequate' (Kinzie et al. 1983). Risk of subsequent cardiac deaths increased with high mediastinal doses and minimal cardiac shielding (Hancock et al. 1993). Carrie et al. (1992) reported relapse at matched field junctions, where dose variation is estimated at 20% even with good technique (Holupka et al. 1993). Inadequate target volume definition is associated with relapse (Perez et al. 1993, Eisbruch et al. 2004).

Dose delivered depends on set-up accuracy (Kutcher et al. 1995, Verhey 1995). Errors of 5-10mm can give 10-50% decrease in tumour control probability (Mitine et al. 1999). In the pelvis, internal organ movement can move tissue in or out of the high-dose zone (Heemsbergen et al. 2007) causing treatment failure and normal tissue damage. Evidence of morbidity from breast radiotherapy exists (NICE guidance 2002), including radiation pneumonitis (Lingos et al. 1991, Bjohle et al 1995). Bates and Evans (1995), reporting on brachial plexus neuropathy, highlighted the need to prioritise risk limitation in technique appraisal and design.

1.3 Treatment practice/conditions common at the start of the research

Historically, radiotherapy delivery was 'blind' insofar that the positioning of treatment beams in tissues could not be verified, with little appreciation that this may not be accurate. Treatment verification film was being used for PI in the USA in the 1970s (Marks et al. 1974), but not in many UK Centres in the 1980s when clinicians at Leeds were using it to check the first treatment of complex-shaped fields.

Relatively primitive set-up methods were used to target volumes planned in 2D. That is, field outline marks on the skin were aligned (as best possible) with the machine field light delineating the radiation beam. The marks (around 8-10mm thick), were painted with gentian violet, using a hand made cotton bud. The patient was straightened 'by eye'. Isocentre height was set using distance to skin measurements or mechanical couch scales. Lead shielding blocks were manually positioned.

Computer-controlled planning, treatment and imaging technology were still under development. Treatment simulators were few and, where available, used only for limited types of treatments. Radiographers were not involved in research or multi-disciplinary collaborative groups, nor expected to input to practice issues. QA was limited to basic checks of equipment and radiation beams for 10cm square over-couch fields, with no contribution being made to the main factors involved in accurate treatment delivery.

1.4 Theme of the submitted research and overview of its impact

The research initially addressed treatment accuracy and reproducibility, and was unique in that it specifically compared different techniques used within one Department for one body site. Factors causing errors were identified and addressed. Accuracy improvements from sequential studies resulted in principles being developed and widely used. This work led to multi-disciplinary collaboration, so that the principles became embedded in national guidelines, QA standards, and clinical trials which subsequently implemented standardised techniques, monitored by PI to specified accuracy tolerances.

Widespread shortages of staff and equipment reduced local ability to implement routine, quality developments which increased treatment set-up times.

Radiographer training with new techniques and the increasingly complex new technology required adequate time and high skill levels. The aims were widened to address:

- Practice improvements to optimise treatment accuracy
- Radiographer and equipment shortages locally and nationally
- Relevant aspects of radiographer education

The work developed radiotherapy quality in the following ways:

- Accuracy/quality related contributions to the first national radiotherapy quality standards and practice guidelines
- Unique, quality related contributions to books written from within other disciplines
- Development of appropriate radiographer staffing structures and an evidence-based national staffing formula
- BTE efficiency study and work with the RCR on national radiotherapy resources
- Unique, education and training material to underpin high quality practice

The work led to a textbook being written, used worldwide by radiographers and oncologists. Designed as a clinical practice quality manual, this describes evidence-based principles influencing treatment accuracy. From an extensive publication record (App. I), the submitted works, spanning a 20 year period (Table 1), reflect the relationship between numerous linked quality factors and knowledge of related issues, as outlined above. They include quantitative analysis based research papers, reviews and books as an evidence-base for high quality radiotherapy practice and clinical services. The early, clinical work, supported by research, led in this professional field and underpins current practice.

Table 1. Summaries of papers submitted.

Published Work	Summary of issues addressed
Radiotherapy accuracy studies	
1 Griffiths SE, Pearcey RG (1985) The reproducibility of large lead protected radiotherapy fields to the abdomen and pelvis.	Accuracy of 'dogleg' techniques studied, identified factors causing various types of errors. Recommended changes to techniques, equipment usage and design.
2 Pearcey RG, Griffiths SE (1985) The impact of treatment errors on post operative radiotherapy for testicular tumours.	Target tissue/nodes missed due to treatment inaccuracies. Recommended planning margins round target tissue, to allow for inaccuracies. Assessed the potential clinical impact of node miss and increased margins.
3 Griffiths SE, Pearcey RG (1986) The daily reproducibility of large complex-shaped radiotherapy fields to the thorax and neck.	Assessed accuracy and errors for mantle technique, with recommendations for practice improvements related to both patient and shielding positioning. Areas containing disease were shielded on 11% of occasions, (no patients relapsed at 1986).
4 Pearcey RG, Griffiths SE (1986) An investigation into the daily reproducibility of patient positioning for mantle treatments.	Reported accuracy achieved after mantle technique improvements had reduced some types of errors. Identified the expected accuracy achievable to assist in clinical film analysis and decisions. Accuracy importance at field junctions stressed.
5 Griffiths SE, Pearcey RG, Thorogood J (1987) Quality control in radiotherapy: the reduction of field placement errors.	Reported much improved accuracy and decreased occurrence of node miss for 'dogleg' patients, following changes in set-up methods and equipment. Identified the size and type of error causing node miss to inform PI analysis at the start of treatment.
6 Griffiths S E, Khoury GG, Eddy A (1991) Quality control in radiotherapy during pelvic irradiation.	Studied different set-up/positioning methods, showing improved accuracy using lateral lasers and tattoos. Stressed using known accuracy limits to plan field margins. Recommended continuous QA checks for technique and equipment, and use of real time PI.
7 Griffiths S, Stanley S et al. (2005) Recommendations on best practice for radiographer set-up of conformal radiotherapy treatment for patients with prostate cancer: experience developed during the MRC RT01 trial	Recommended evidence-based practice based on three-dimensional accuracy from multi-centre trial PI analysis. Detailed the use of tattoos and lasers for aligning pelvic fields in the lateral and CC directions, and isocentre height setting methods. Highlighted three practices that correlated with inferior accuracy in one axis in three Centres. All participating centres changed their practice.
8 S Stanley, S Griffiths et al. (2008) (MRC RT01) Accuracy and reproducibility of Conformal Radiotherapy using data from a randomised	Presented overall three-dimensional accuracy results and evidence-based imaging conclusions from a multi-centre trial. Concluded that conformal fields were delivered within the accuracy requirement of

controlled trial of CFRT in prostate cancer	3mm. Showed that MLC and Electronic PI use was associated with significantly fewer errors than external shielding and port film.
Publications related to, and as a result of the impact of 1-6	
9 Griffiths SE (1986) Reproducibility in radiotherapy.	Peer education article describing treatment accuracy issues, errors and causes found, explaining the key factors for practice improvement to avoid or reduce the errors
10 Griffiths SE (1989) Hit or Miss - is perfection achievable in radiotherapy?	Education article for peers/clinical practitioners describing further causes of treatment error, key accuracy factors, improved patient positioning methods and equipment issues including couch sag.
11 Griffiths SE (1990) Radiotherapy quality control: portal and verification films.	Education article on portal image methods in verification, using current linacs, including exposure factors and example images
12 Griffiths SE (1997) Section 2.2 The radiographers view. In: The design of radiotherapy treatment room facilities.	Input to physicist guidelines, of radiographers' requirements as the principal users of equipment, particularly under high workload conditions. Ergonomic factors considered included those influencing: patient safety/comfort, range of practice possible, accuracy and efficiency achievable; safe working conditions.
13 Flynn A, Griffiths SE, Joslin CAJ (2001) Chapter 6 Safe Practice and Prevention of accidents in after-loading (brachytherapy).	The radiographer input to a textbook written by oncologists and physicists, including quality and safety checks during and relating to treatment preparation, programming, set-up, patient monitoring, radiation exposure monitoring and operator training.
14 Griffiths SE (1999) Writer/lead- Section 3 Treatment Delivery; App. 4 Reproducibility in Treatment Delivery. In: RCR Guidelines for external beam radiotherapy.	Practice and safety principles and related knowledge from Leeds, in particular treatment delivery and accuracy verification, were embedded in these first national radiotherapy quality guidelines with recommendations for the full range of clinically related processes.
15 Trial Management Group (1999) Standardisation of Breast Radiotherapy (START) Trial.	First multi-centre trial to specify a PI verification check, with field matching methods tested by the QA programme.
16 Sydes MR, Stephens et al. (2004) Implementing the UK MRC RT01 trial: Methods and practicalities of a randomised controlled trial of conformal radiotherapy in men with localised prostate cancer.	Trial aims and QA to validate clinical results for the then innovative conformal treatment. Specifications include a radiographer group (RTIG) to monitor treatment delivery by PI and ensure this to be within an accuracy margin of 5mm, with an imaging and correction protocol.
17 Mayles WPM, Moore et al. (2004) Questionnaire based quality assurance for the MRC RT01 trial of dose escalation in	Describes the trial QA process and a comprehensive QA questionnaire detailing factors relevant to treatment accuracy, including a section on treatment set-up and

conformal radiotherapy for prostate cancer	delivery. Confirmed the usefulness and validity of this self assessment process
Publications on wider quality issues arising from accuracy studies and related developments	
18 Probst H, Griffiths SE (1995) Increasing the work-speed of radiographers: effect on the accuracy of set-up of a complex-shaped cranial field, part of a matched cranio-spinal junction.	Identified that when radiographers worked under time pressure, setting-up a complex technique, accuracy decreased. Highlights risk issues related to equipment and staffing shortage.
19 Short CA, Griffiths SE (1996) Radiotherapy: Developments, contradictions and dilemmas.	Invited review of practice and technology developments, considers QA time for new equipment, PI, potential accuracy and quality benefits, hyper-fractionation, and conflict in managing implementation considering staffing issues, costs and training
20 Griffiths S (1999) Therapy Radiographer Staffing for the treatment and care of cancer patients.	Guest Editorial. Described and justified a radiographer staffing structure for a large radiotherapy department, allowing for practice research and development, and continuing radiographer education.
21 Griffiths S, Delaney G, Jalaludin B (2002) An assessment of Basic Treatment Equivalent at Cookridge Hospital.	Quantified the effect of techniques and technology on fraction time, in collaboration with Australian oncologist experts. Provided a formula to assess treatments per unit time, achievable with a given number of linac staff.
22 Probst H, Griffiths S (2006) Moving to a High-tech Approach to the Irradiation of Early Breast Cancer: Is it possible to Balance Efficacy, Morbidity and Resource?	Examined evidence for more complex techniques, related to accuracy and morbidity for disease sub-groups with differing needs/risks. Related the extra resources needed, in a climate of resource limitation, to benefit, for these sub-groups.
23 Griffiths S, Craig C, Abraham M (2006) Radiographer roles and risk management in Radiotherapy.	Quantitative analysis of a national survey identified an evidence-based formula for radiographer staffing to achieve a given workload with minimised risks, allowing for practice QA, training, PI, applicable to any department. Adopted for National guidance
Quality manual incorporating all quality findings	
24 Griffiths SE (2008) Radiotherapy: Principles to practice. A practical manual for quality in treatment delivery. Second edition.	Describes evidence-based practice guidelines and principles derived from 1-23. Topics include all relevant knowledge required by practitioners relating to technical practice, including radiobiological and equipment factors, data checking systems, an imaging and verification section, accuracy principles applied to techniques including contemporary approaches, staffing and management requirements for high quality radiotherapy.

1.5 Seminal accuracy and reproducibility research at Leeds (1983-1991)

Radiographers in Leeds were aware that reproducible positioning of the light beam on a patient's skin marks was not always achievable and the fit of shielding block to marks was variable each day. As a clinical practitioner, in 1982, I used PI to demonstrate that this produced large variations in the anatomy treated, by identifying bony structures and treatment field edges recorded. I then initiated a research programme using PI in prospective studies of technical treatment procedures and their accuracy working with oncologists in the Leeds Clinical Department, (and gaining funding in 1983). The research aimed to modify techniques in order to improve reproducibility and optimise accuracy, initially using large complex-shaped fields to the trunk. Each of five sequential studies, built successively on information gained, and established the effect of changes made to techniques. A sixth study using pelvic fields aimed to establish which patient position and set-up method gave the best accuracy, comparing outcomes with previous results.

Uniqueness and originality at the time of publication

- PI not previously used for prospective accuracy studies anywhere in the world
- Compared accuracy of different techniques within the Centre including within same patient
- Sequential studies using film specifically as a tool to develop techniques
- Achieved progressively improving accuracy in sequential studies (ESTRO prize awarded for this)
- Suggested lateral field shift was due to patient rotation at planning compared with treatment; initiated alignment of lateral tattoos and lasers to address this
- First UK clinical impact report (1985), with recommendation for routinely planning normal tissue margins round target tissue to allow for inaccuracies
- Using PI derived accuracy standards for clinical decisions and margins
- Principles developed and used across practice, embedded in National quality guidelines and later used in first clinical trials taking account of treatment accuracy, also in pedagogic material, textbook with unique content

- The first UK publication (1) reporting a film based treatment accuracy study, also the first radiographer led study and paper authorship
- Later the methods were tested and built-on in a multi-Centre trial

The outcomes established the origins of treatment inaccuracies and identified and implemented changes in multi-disciplinary practice throughout the radiotherapy process, thereby improving accuracy and reproducibility. The changes included discontinuation of painted skin marks and the introduction of whole-body patient positioning, using (i) appropriate customised supports, (ii) tattoos aligned with lasers, (iii) unified set-up conditions through planning and treatment, (iv) improved shielding methods, (iv) changed aspects of equipment usage. The magnitude and frequency of errors, arising at the start of, and random errors occurring throughout, treatment, were greatly reduced.

1.6 Involvement in the first clinical trials which took treatment delivery accuracy into account

The MRC RT01 radiotherapy prostate trial (1998-2002) aimed to establish whether conformal (small) treatment volumes, enabling dose-escalation, improved cure without increasing morbidity. Because of the increased risks, the validity of clinical results relied on target tissue being accurately irradiated. This was the first trial to specify a treatment delivery accuracy tolerance, monitored and corrected throughout treatment for all patients, using PI. In multi-Centre clinical trials, standards are important to avoid 'comparing apples with oranges' requiring a QA process to ensure uniformity in dose-delivery and contouring/margining of the target volume, for all participants. Two process documents, one with the Leeds evidence-based practice principles, one from the pilot study site (RMH), appended the trial protocol (App.I, III). Explicit involvement of radiographers from participating Centres was seen as key to ensuring achievement of accuracy. Being on the management and QA groups, I chaired the RTIG QA sub-group, with roles including the development of radiographer led PI analysis and sharing expertise in a then relatively innovative treatment protocol (MRC 2000). PI data, and a supplementary radiographer questionnaire were used to inform two accuracy papers.

The START trial aimed to establish the optimum radiotherapy fractionation for early breast cancer patients. UK practice varied, linked to linac and staff availability. The control (2.0Gy x 25#, 5 weeks) was compared with trial A (3.0Gy or 3.2Gy x 13#, 5 weeks) and trial B (2.7Gy x 15#, 3 weeks), the regime used by Centres with fewer linacs.

Uniqueness

- START and RT01 were the first clinical trials to involve radiographers in trial management and QA, to consider treatment delivery techniques, and use PI. Stemming from my input they became the first trials to specify treatment delivery technique and, in the case of RT01, detailed patient positioning/set-up methods, subsequently becoming standard practice.
- The two RT01 accuracy studies were the first radiographer led MRC publications.

1.7 Summary

Evidence-based patient set-up techniques, proven to ensure that each treatment is accurately applied, are required for high quality radiotherapy, and good clinical outcomes. This submission addresses aspects of quality in radiotherapy practice especially related to treatment delivery. It reports these progressively, as they evolved from the original seminal work reviewed in Chapter 2, and particularly how this resonates with contemporary practice. Radiographer involvement in research and the development of image-based verification, equipment and QA standards are explored in Chapter 3. Chapter 4 considers wider impacts of the research and its use by others, work on radiotherapy resource issues aimed at enhancing quality, and development of the textbook. Chapter 5 summarises overall outcomes of the work.

CHAPTER 2. ISSUES RELATED TO ACCURACY AND REPRODUCIBILITY, FOR PATIENT SET-UP TECHNIQUES

Following from the demonstration that treatment was inaccurate (section 1.5) the purpose of this Chapter is to show how the seminal research led to modification of techniques in order to optimise accuracy.

2.1 Accuracy related findings and developments from Leeds studies 1- 6 (1984-1991)

Treatments using differing extended FSD techniques for patients with a high chance of cure, including for seminoma (dogleg shaped field to testis and nodes) and later lymphoma (mantles), were studied (1- 5). Six films (after clinical film acceptance) were stored unread. Then the 50% field edges, their planned position and anatomical information were traced and field edge distances from bony points measured.

The shape and position of large complex-shaped treatment fields on the target anatomy was found to be variable, with commonly occurring errors. Types of errors and their likely origins, which included patient and equipment related contributory factors, and their significance, were identified. Some errors were repeated on every film (systematic), while others were random. Field rotation and lateral shift combined to cause observed variations at the field extremity, of ≤ 3 cm on through-couch PA fields where more frequent errors were seen (1). Setting PA fields by gantry rotation and couch height change (without a patient) demonstrated large, equipment related, field rotation ($\leq 5^\circ$) and shift errors. Other errors were partly related to painted field outlines on the skin being prone to distortion and not relating in the same way each day to the anatomy. In 50% of dogleg patients, nodes in the target tissue were missed on at least one occasion. These were in the highest risk tissue on 10% of films (2). A tray mounted field template bearing skin tattoo reference points and shielding alignment outlines (template technique), for supine and prone positions treated over-couch, was more accurate. The findings led to prescribing, technical and setting-up modifications (Table 2).

Mantle studies (3, 4) showed that some of these same error types caused misplacement of each shielding block. Thus errors were multiplied by complex

field shape and magnified by FSD and field size (described with diagrams in 9, 10, 24 pp.248-250). CC shift was larger than lateral shift, one patient having an 18mm inferior border shift, another having systematic 1.5cm field shortening (4). We concluded that lateral field shift arose from lateral patient rotation at planning relative to treatment (4, described in 10, 24 pp.146-7).

Table 2. Error factors, recommendations and outcomes from studies (1- 4).

Paper	Factor identified	Recommendation	Outcomes
1	variably positioned, defective shielding blocks	use individually customised beam shaped blocks with fixed orientation in the beam	change to customised beam shaped blocks, pegged to tray
1	distortion of painted skin marks	discontinue use of skin marks	change to centre tattoos for complex techniques
1	patient skew, contributing to field rotation	use sagittal lasers for positioning, with bony anatomy and tattoos, also for aligning field template in tray	sagittal lasers installed in all treatment and simulator rooms
1	field shape verification needed before treatment	need lead tray for simulation of shielding	in house development of simulator Pb tray
1	greater error on through couch PA fields at long FSD	discontinue this through couch technique	used supine and prone technique, plan and simulate each field
1	treatment L/R lateral field shift relative to planning	modifications to positioning technique	subsequently investigated using lateral lasers and tattoos (6)
2	node miss linked to error on narrow field and in critical tissue	use planning margins round target tissue to allow for treatment inaccuracies	Field width increased, margin principle extended to other sites
3 4	CC variations in field edge to be a matched junction subsequently –could give under/over dosage at junction	Use PI to determine edge of matched field	Use PI, reconstruct set-up of original treatment when planning junction, and for treatment of new field
3	better positioning required in longitudinal and lateral directions	Use lasers and tattoos at stable points to help with whole-body alignment, feet positioning	Introduced more widely spaced positioning tattoos in CC axis and relevant stable/bony anatomical points, aligned with the sagittal laser
3	skin mobile with position	Need for improved patient positioning	Standardised and effective supports used, pillows

		throughout planning and treatment to stabilise relationship of skin to internal anatomy.	discarded, whole-body positioning introduced (without rigid immobilisation) for all procedures Added widely spaced tattoos in L-R axis at shoulder level for mantles.
4	skin movement threatens dosimetry at junctions	Patient kept still throughout matched fields within one fraction e.g. breast/SCF	Matched fields carried out on one machine (previously fields treated on different energy machine)
4	thick lines on template and magnification effect on block position	Thinner lines and fixed blocks needed	Developed fixed blocks

Planning safety margins round the target tissue, by a 1cm increase field width, was shown in a second series (5) using the improved template technique, to have reduced node misses (Table 3). Field rotation was virtually eliminated, but four patients treated using the original 8-10cm tattoo separation had large errors, demonstrating that widening the tattoo spacing generated this improvement (described in 10 and 24, pp.144-5).

Finally various set-up methods of rectangular pelvic fields were studied within the same patient, lying on a hard couch top for both supine and prone positions, using repeated simulator images to establish the most accurate method (6). Centring on a central tattoo proved more accurate than using the standard inferior painted field limit. Accuracy for the prone position was inferior to that for the supine position, but using lateral tattoo and laser alignment accuracy for both positions was similar and patient rotations were largely eliminated. The accuracy achieved was compared with that for the pelvis in earlier studies (Table 4). Set-ups were repeated with a thin soft mattress introduced, which made accuracy unpredictable.

Table 3. New practice used in papers (5, 6). Results compared with studies (1, 2) and outcomes.

Paper	New practice/principle used	Results compared with 1,2	Outcomes
5	Template reference points aligned with widely spaced tattoos, and sagittal laser	Field rotation virtually eliminated	New practice sustained, extended principle to all techniques
5	Field width mostly 9cm	Node miss rate substantially reduced	New practice sustained, extended principle to all techniques
5	No through couch long FSD fields	Systematic PA lat shift and field rotation errors halved, random error reduced	New practice sustained, for long FSD techniques
5	Template with fixed beam shaped blocks used (aligned manually on tray)	Random field width (shielding) error smaller but remaining error magnified by long tray to central axis distance	Need dedicated fixed block/tray base per field to reproducibly align shielding in beam. Need simulator block tray
5	Positioned at planning using fluoroscopy and sagittal laser for straightness, feet apart to reduce lateral rotation	Systematic lateral shift errors thought due to differences in positioning between simulation and treatment, and changed table surface/rigidity (10,24)	Consistent stable position through planning and treatment needed for all techniques, options studied (6) also couch sag
6	Lateral lasers to reduce lateral roll	Much improved lateral shift using lasers/tattoos	Lateral lasers/tattoos, used for all suitable techniques
6	Fields aligned with centre tattoo rather than marks	Improved pelvic field accuracy in CC direction	Centre tattoos adopted for all techniques
6	Hard table top required for accuracy	Improvement in accuracy may have partly been related to discontinued use of flexible couch window	Avoid using flexible couch window or soft mattress/pads where accuracy required

Table 4. Improvements for lateral shift error, % of incidence of $\geq 5\text{mm}$, $\geq 10\text{mm}$, mean, and SD.

Paper	prone				supine			
	$\geq 5\text{mm}$	$\geq 10\text{mm}$	mean	SD/mm	$\geq 5\text{mm}$	$\geq 10\text{mm}$	mean	SD/mm
1,2	65	23	6.0	2.6	53	12	4.7	3.0
5	29	5	2.4	2.4	16	3	1.9	2.7
6	15	0	2.0	1.8	12	0	1.6	1.4

2.2 Review of studies (1 – 6)

Radiotherapy involves a complex series of procedures, each based on a principle which may be flawed because of incorrect assumptions, resulting in treatment not being delivered as planned. These publications opened up a new field of knowledge concerning the origins of errors and technique pitfalls. They drew attention to the incorrect assumptions that equipment accuracy is adequate under every condition of use, and that the skin or shell which bears surface marks relates consistently to target anatomy.

It had been assumed that planning only the anterior field then treating this PA through-couch was superior to turning the patient over and planning both fields. However, unavoidable equipment-related error at long FSD, and beam divergence effects, meant that the under-couch field should also have been simulated (which was not possible at long FSD). Our findings raised awareness that for this technique, and possibly others, the achievable machine accuracy was inadequate, and not covered by QA checks. Recommendations included continuous set-up QA programmes using PI (Ch. 3), and establishing equipment-related error for techniques practised. Discussion continued until standard linac field sizes increased to 40cm square, doglegs were changed to para-aortic fields, and mantles were replaced by smaller 'involved' fields which reduced normal tissue dose and the incidence of second cancers (Koh et al. 2007). In the mantle studies (3, 4) the target volume was partially shielded by 1-2cm on 21% of films, known disease being shielded on 11% (3). The reduced received dose could have a significant effect on outcome for lymphoma (Kaplan 1966, RCR 2006). The research contributed to the clinical management of lymphoma. Improvements in accuracy and technique since the 1980s contributed to reduced complications (Aleman et al. 2003) including cardiac death (Hancock et al. 1993, Provencio et al. 2008). Because of remaining risks following radiotherapy, chemotherapy is the current curative treatment of choice (Canellos 2005, Connors 2005) for Hodgkin's Lymphoma.

Margins were then adopted for all sites treated curatively in Leeds (2), preceding the ICRU defining the planning volume as the target volume plus a planning safety margin to allow for set-up variability (ICRU 1993, 1999). We aimed to establish achievable accuracy for each technique, stressing the

importance of improving techniques to reduce variability, and using known accuracy limits to determine margins. The uncertainties and diverse factors shown to be associated with treatment accuracy and reproducibility became recognised by involved disciplines, later reflected in publications, such as in the quote from Verhey (1995), 'skin markers and how used are now recognised as the key to accuracy', and Bentel (1996).

In particular, publication (1) was *seminal* since it:

- identified equipment factors contributing to errors
- stated intention to re-investigate accuracy after technique modifications
- concluded that errors may be occurring generally and that changes in techniques may reduce their frequency and magnitude (quality control)
- was the first radiographer led study and UK treatment accuracy publication

Few, medically-led treatment accuracy publications existed. Richards and Buchler (1975) considered variations of >1cm in the pelvis and, in common with Byhardt et al. (1978) and Marks et al. (1974, 1976), recorded ≤ 3 -4cm inaccuracies. Rabinowitz et al. 1985 described varying error magnitude with body site. Little data existed for pelvic fields. Although, in some studies, technique was implicated and some procedures adjusted subsequently, publications mainly related to the usefulness of PI checks and corrections rather than technique comparison and improvement. Few studies have compared different set-up methods, for the same site within the same Centre (Catton et al. 1997, Mowbray and Bonnet 2002). Rosenthal et al. (1993) and Soffen et al. (1991) reported improved accuracy for the prostate using rigid immobilisation in one Centre compared with soft immobilisation in another Centre. Rigid devices have many drawbacks, and were not found to improve accuracy compared with carefully applied set-up methods (Creutzberg et al. 1996) for pelvis, or thorax (Halperin 1999).

Over studies (1-6), random errors (SD) were minimised (Table 4). The median CC shift range (6) was lower than in other pelvic accuracy studies reported by Lennernäs et al. (1995), these included Gildersleve et al. (1994b) using interactive PI intervention, and Rosenthal et al. (1993) using rigid immobilisation. Retrospectively, the finding that introducing a foam mattress

made accuracy unpredictable (6), questions the validity of the results for patients supported on a less rigid, treatment-table window (10). The results are valid for rigid couch tops. Clearly the significant accuracy improvements achieved resulted from multi-disciplinary method changes (Tables 2, 3), rather than the routine use of PI.

Treatment verification, measurement and identification of error components

Verification film images (11) were difficult to assess. However, I and a Leeds colleague gained sufficient expertise (1-5) that our independent manual measurements correlated to 0.5mm. Measurements on higher quality fluoroscopy images (6) correlated to the same precision. The comparison was absolute, as was the relative accuracy achieved. We recommended PI on the first few fractions to identify, and make early correction of, systematic errors, as did Marks et al. (1976) and Mitine et al. (1991), stressing the need for careful measurement, since errors of ≤ 1 cm had been missed on clinical PI checks. Others reported significant errors on clinical films studied retrospectively (Marks et al. 1974, Kinzie 1983).

Systematic error can be corrected by a set-up change, whereas random error cannot, and where large random errors occur on many patients, technique improvement is needed. Statistical analysis is necessary to identify systematic errors large enough to require correction. In (1-4) we used each patient's median error value, and established ranges for each error type, suggesting a range of 15mm, 67% of treatments being within 6mm (4). In (5) onwards, we used systematic and random (SD) values. From all our series we derived the size of error likely to be systematic and clinically significant, to assist decision-making from a first film (5). This set a local standard for the overall expected accuracy for a technique, necessary for margin determination (Creutzberg et al. 1996, Hurkmans et al. 2001) and verification protocols. Systematic error is better identified after three fractions and correction optimised (de Boer et al. 2001, 2002), a widely used practice (Dale 2003). This supports our view that the first few films are critical for detecting significant errors (3-6). Weekly imaging is recommended for 3mm tolerance, e.g. for prostate (8, Hurkmans et al. 2001). PI verification guidelines related to site, clinical need and expected accuracy are now available (RCR 2008).

Relevance of seminal work to technology developments and contemporary capabilities

The principles developed in (1-6) underpin, and are essential to, the geometrical accuracy of radiotherapy delivery (24), which has escalated risks with contemporary methods (or fewer fractions) as follows. Increasingly complex computerised technology and MLC provide intricately shaped and dynamically changing fields, allowing CFRT to 3D volumes, using IMRT. Scanning beams, or multiple small beams, each sculpted to deliver the required dose and avoid nearby tissue, give steep dose-gradients within one or more overlapping target volumes. In Tomotherapy, the patient/couch moves slowly so that small helical beams, varying in shape and intensity, treat a continuous length of intricately shaped target volume to achieve a dose distribution planned by the machine (Griffiths 2007). Patient positioning methods remain crucial to achieving the planned tissue irradiation despite equipment improvements and increasing capability for intricate shaping and technology assisted delivery methods. Difficulty in achieving complex-shaped fields (3,4,10, 24, Kinzie et al. 1983, Marks et al. 1976, Taylor et al. 1990, Welten et al. 1993, WHO 2008), is highly relevant to current techniques.

2.3 Summary

The research, which contributed to the clinical management of lymphoma, led to improvements in accuracy to within currently expected norms for the pelvis, achieved by changes in multi-disciplinary prescribing and planning practice, i.e.:

- consistency of positioning through planning and treatment
- whole-body patient positioning using lasers and tattoos, standardised soft supports
- discontinuing skin marks
- changes in equipment, its QA, and usage
- establishing accuracy standards for clinical decision-making, from PI analysis
- allowing margins around target tissue

These principles were adopted internationally and later used for MRC RT01 trial patients, so proven across Centres (7, 8).

CHAPTER 3. PROFESSIONAL AND QUALITY ASSURANCE

CONSEQUENCES OF THE SEMINAL RESEARCH

This Chapter explores some consequences of the research, relating particularly to radiographers, equipment related quality issues, QA development and clinical trials.

3.1 Radiographers, education, and research involvement

Radiographers need knowledge of accuracy principles. These were presented in conferences (App. II) and education texts, including a distance learning technique module (App. I), articles summarising the studies with sources of error and implications for radiographer practice (9, 10), and PI verification (11). Texts suggested that practitioners question techniques (RCR 2010) and assess equipment accuracy effects. I undertook educational initiatives (App. IV) including technical refresher courses for radiographers returning to practice. A textbook (App. I, V) Griffiths and Short 1994), revised in 2008 (24) is discussed in Chapter 4. Other clinical radiographers became involved in technically based research (6, 18, 19, Quinn 1993, App. VI), adding to publications from Leeds. I established a unique 'Imaging research' post, the appointee (1995) being directed to continuing PI accuracy study (Stanley 2003) and co-opted to RT01 (7, 8). Most accuracy studies are now radiographer led as a developing practice role (23) and several Centres have research radiographers (Davies and Rawlings, 2009). The patient care role of UK radiographers has always been emphasised, their unique and critical role in achieving high quality radiotherapy often being underplayed. The current role of the majority as clinical treatment experts and technical specialists, results from increased recognition of their unique skills and ability to contribute greatly to treatment quality following from successful research activity. They are now widely involved in research and development, publication, multi-disciplinary conferences, and collaborative working groups, clinical trials and national radiotherapy research support networks including ACORRN, launched in 2005 (Heap and Stones 2009), UKCRN and NCRN. Now the COR has a research strategy (COR 1994, 2005, Harris and Beardmore 2009), organises meetings and funds research through its industry partnership scheme.

3.2 Equipment design, accuracy and quality effects

Equipment effects on accuracy became another aspect of my quality related work. We identified (3, 10) mechanical couch scale inaccuracy of $\leq 1\text{cm}$, one linac optical system moving with diaphragm rotation, and couches moving if knocked or leant on during set-up, all of which were discussed with physicists and manufacturers to be improved in subsequent design. Fixed shielding block trays and methods of checking shielding before treatment, were developed. Couch-top design clearly affected isocentre height setting accuracy. I supervised a study (Quinn 1993), which found $\leq 20\text{mm}$ sag error for mylar couch windows and $\leq 16\text{mm}$ for “tennis racquet” sections, and varying daily for each patient (10, 24 and App. II). Greer et al. 1998, Creutzberg et al. 1998 also documented problems. Physics staff designed more rigid panels and we developed vertical ruler devices to stand on the couch in the isocentre plane for setting the isocentre HAC to $\pm 1\text{mm}$ (previously planned to 5mm) using lateral lasers (10). Equipment scales were calibrated in 5mm increments. Still used, these devices allow a true patient HAC setting unaffected by couch tilt or sag (which cannot be registered by integral couch scales). Others adopted this principle, and achieved the best HAC accuracy in RT01 (7). As a result of standardising in-house developed treatment accessories and conference presentations, opportunities to discuss and collaborate with manufacturers arose and I was able to influence design. Ultimately, carbon fibre panels, tops and overlays were commercially introduced, as were positioning accessories and shielding systems with individual fixed block trays coded into parameter verification systems.

An invited presentation (IPEM meeting, 1990, App. II) formalised the radiographer (clinical user) requirements on the design of treatment facilities (12, Table 1). Equipment design considerations influencing efficiency and accuracy and ease of set-up included (i) isocentre height/treatment head dimensions, (ii) wedging system (accessibility, viewing of set-up, lifting issues), (iii) optical systems (visibility, accuracy, compatibility with PI), (iv) mechanical scales and indicators (backup to electronic), (v) handset and movement controls (safety, variable speed smoothness), (vi) treatment couch design (height range, top construction). Record and verify systems, computer control (simplicity, PI facility) and control area privacy contribute to error prevention in programming

treatment. The potential for serial errors with computer control and parameter verification was identified by Short (1992), Leunens et al. (1992), Walker (1994), Fraass et al. (1998) and (19). Such (serious) errors occurred much later when computerised settings had become the norm, (IAEA 2000, French 2002, Patton et al. 2003, DOH alert 2005, DOH 2005). Over reliance on automated systems and performance of associated checks was termed 'involuntary automaticity' (Toft and Mascie-Taylor 2005).

3.3 Development of National Radiotherapy Quality Assurance guidelines

Early in the seminal work, it was established with our physicists that linac QA procedures were too limited to assure accuracy for all techniques used. Procedures were broadened locally, later leading to extended equipment QA recommendations (IEC 1989, 1996, Lillicrap et al. 1998, IPEM 1999). Professor Joslin (Leeds), with knowledge of our studies, was tasked with setting up Quality Assurance in Radiotherapy systems, as a national requirement (DOH 1994). I influenced development of this with knowledge accrued during the studies, and subsequently contributed to a chapter on safety in an oncologist and physicist led brachytherapy textbook (13, Table 1).

The principles from (1-6) and quality related knowledge were applied in a new collaborative multi-disciplinary group role to develop the first (national) generic radiotherapy process guidelines (14). I was lead author on treatment delivery, reproducibility and pre-requisites comprising (i) treatment data, checks and transfer; (ii) patient shape, position and movement, (iii) treatment verification, (iv) patient transfer between machines, and also the appendix 'Reproducibility in Treatment Delivery'. Many other recommendations were influenced especially for planning processes relating to reproducibility, including transfer and programming of treatment parameters. The guidelines were later used in the DOH Cancer Services Peer Review standards and the principles echoed in international quality reports (WHO, 2008, RCR, 2010).

3.4 Development of image based verification of radiotherapy

Imaging has undergone massive development since the start of the Leeds work. Treatment simulators used diagnostic x-rays in planning or verifying the position treatment fields, relative to the bony skeleton, in 2D. Methods were not

available to check, correct or improve the accuracy of treatments until the late 1970s when treatment verification film, recording a whole fraction became available (1-5). Treatment check films then gave an improved image which could be double exposed to show the field in relation to surrounding anatomy at the start (or end) of a fraction (11), achievable later via electronic-PI systems (Meertens et al. 1990).

As a consequence of publications (1-5), Leeds secured a DOH grant (1990) to evaluate electronic PI, involving installation of a prototype device, and subsequent involvements in developments. Valuable principles for clinical use, and tools needed for image analysis, were identified. Leeds' presentations, including by radiographers, were prominent at the first UK PI conference (BIR 1992, App 11). We suggested that real-time imaging would allow easier monitoring and correction (6), later found to be impractical routinely (Dale 2003) because it increased fraction time by around 10 minutes. CT was developed and the images allowed soft tissue visualisation and improved accuracy in 3D target volume localisation (Rothwell et al. 1983). Later CT simulation eliminated discrepancies arising between simulation and treatment (Rabinowitz et al. 1985), now enhanced by PET-CT identification of areas of active tumour. This development necessitates treatment verification of soft tissue targets by 3D visualisation using CBCT, MRI or ultrasound, allowing necessary checks, intervention and correction before treatment proceeds (24). CBCT is now commonly used in verification imaging which begins at day zero, when a check for gross error is undertaken.

Imaging and organ motion

Organ motion, from physiological actions such as breathing, presents a challenge to treat the target tissue accurately despite careful planning and delivery relative to bony anatomy. Breathing movements can be accounted for using 'slow CT' planning images and breath hold technology on treatment. For breast treatments this significantly reduces heart and lung doses (Remouchamps et al. 2003, AAPM 2006). The shape or position of internal pelvic organs varies with rectal filling, increasing the uncertainties for prostate treatment accuracy. Tinger et al. (1998) used margins approaching 1cm, de Crevoisier et al. (2005) linked rectal filling to geographical miss and toxicity,

while Heemsbergen et al. (2003) found tumour control significantly decreased in patients with rectal filling visible at planning. Stereotactic X-ray PI technology (24) linked to computer controlled feedback and robotic dynamic corrections, by tracking target tissue (Stack 2009, Aitken and Corsini 2010) may be the ultimate accuracy solution. However these technologies are unlikely to be used routinely in the foreseeable future because of their cost and inability to provide soft tissue visualisation. Real time visualisation and treatment beam positional adjustment for changes arising from organ motion (IGRT) is currently used for sites such as the prostate.

3.5 Accuracy and clinical decision-making from image analysis and protocols

At the start of RT01, PI was new to most Centres. Films could now be digitised (Stanley 1999) allowing software assisted analysis. One image analysis methodology was clinician-led whilst several were radiographer-led, with clinician review. The trial provided opportunity for radiographers to develop PI analysis skills (Suter et al. 2000). A UK audit of verification practice (Stratford et.al. 2006) showed few Centres had protocols for any site except the pelvis, where the protocol was based on RT01 reflecting the trials' influence on UK practice (App.I, MRC 2000, 15).

Since RT01, and wider use of imaging technology, radiographers' roles include daily treatment decision-making and interventions based on image analysis. Training and experience in image measurement and evaluation, for each type of image, is required for staff making decisions (RCR 2008, 2010, WHO 2008). In Leeds, we had found that training on PI software enhanced analysis, making routine radiographer evaluation viable. In RT01, software analysis was linked with higher error reporting rates than manual film measurement, and with increased accuracy (8). Each Centre now uses decision rules and guidelines, based on their own practice needs and literature such as the RCR (2008) geometric verification guidelines (where I was the expert reviewer, App. III). Protocols may include correcting errors only after they are seen twice, and/or a percentage of the error (the rest being random), or by action thresholds using the known error SD of the technique (Dale 2003). Radiographers help to devise protocols they use in assessing acceptability of each set-up, decision-making

and interventions, requiring specialist expertise on priorities for particular situations.

3.6 Trials, treatment delivery accuracy and QA developments

An EORTC trial QA publication (Valleya et al.1998) refers to reproducibility of dosimetry but not geometrical accuracy. The CHART trial (Saunders et al. 1989) funded radiographers at participating Centres to undertake treatments (10), but not formal monitoring of treatment accuracy, or QA (Aird et al. 1995). The MRC Radiotherapy Working Party Steering Group later set-up a radiotherapy trials structure, the first trial being RT01, also part funding the START trial.

START trial

Input to START from 1995, as the radiographer member of the Protocol Writing Group and Trial Management Groups, included advice on breast treatment delivery techniques and input to publications (START trial management group 1998, 1999, 15 App.I, III). Linac QA was undertaken by physicists to check equipment accuracy to 2mm tolerance, assumed to be the treatment accuracy achievable. There was a big gap between this and the treatment delivery accuracy actually achievable. Crucially for the later safety and credibility of the trial, my input resulted in patient position and treatment delivery technique being included in the trial protocol. This then required that patients remain in position, without any movement, throughout treatment of the matched tangential and SCF fields to prevent junction dosimetry being compromised by surface marks moving relative to underlying tissues, between fields. My observations of the skin movement effect had not been recognised by physicists and oncologists, since common practice used different machines (energies) to treat the two matched zones. The matching of fields was then unpredictable, and considerable morbidity could accrue from an overlap. This was another example of techniques being based on treatment planning, without recognition of the practical limitations. The new awareness led to national changes in practice. Discussion followed about doses received in the brachial plexus if all fields were the same (higher) energy, to avoid overdosing this structure. An enquiry into the safety of breast techniques was underway (Bates and Evans 1995), prompted by mass litigation from patients with radiation morbidity, especially brachial plexus neuropathy following breast radiotherapy.

Junction matching became a key issue and before accrual (1999) pre-trial QA visits to Centres assessed methods of beam matching and isodose reference points. Target volume review and dosimetry measurements used a custom-made phantom to measure delivered doses (Venables et al. 2000, 2001). Quality control practice was also surveyed (Venables et al. 2001). Some Centres were required to modify their matching/technique prior to entering patients (Winfield et al. 2002). For each patient a start of treatment PI was checked with the planning image by the QA radiographer (at Mount Vernon Hospital). Serial PI was undertaken for a subset of patients to study lung depth reproducibility, aimed to establish a UK norm (Venables et al. 2005). QA assessments were expected to have a unifying effect on techniques and ensuring treatment delivery quality. Before this, patient position and treatment delivery technique, were not part of trial QA. Now all trials include this. Fifteen fractions proved adequate, reducing resources needed for breast cancer radiotherapy (START Trialists, 2008).

MRC RT01 trial

CFRT was new to most Centres involved and pre-trial visits were not feasible, so a comprehensive QA questionnaire was developed. This had specific requirements covering all processes from volume definition to treatment delivery and verification, my major input being to processes which would influence accuracy and reproducibility (17). Centres had to satisfactorily complete this and an outlining exercise before entering patients. I addressed any technique concerns the returns raised. Later, the research radiographer addressed issues arising on QA visits. The questionnaire proved to be a thorough and successful self-assessment tool to ensure that trial standards were met. The RT01 QA process is now used for all IMRT related trials.

The RTIG was a crucial part of trial QA (16, 17). This provided an unprecedented opportunity for radiographers from involved Centres to discuss treatment delivery, verification and reproducibility issues and to learn from the experiences of others for CFRT prostate set-up. Sharing imaging results and knowledge, exploring differences, allowed development of consensus for best practice, enabling accuracy and quality developments within Centres. (These

recognised benefits from radiographer input to RT01 led to similar involvement in later trials. ACORRN recommended that a radiographer group be included for radiotherapy trials involving technical developments). RTIG members identified that using the lateral tattoos aligned with the anterior tattoo to set the field in the CC axis (preventing AP pelvic tilt) gave better accuracy than using the anterior tattoo alone. All Centres changed to this practice, with one exception, where resulting CC axis accuracy was inferior. RTIG recognised that the position or shape of the prostate target volume, and thus tissue in the high-dose zone (7), changed with rectal filling variations and moved relative to surface tattoos and bony anatomy used in set-up and accuracy monitoring. Additionally patients could not comply with the protocol for bladder and rectal filling, so bladder filling instructions were changed. Intervention aimed at standardising rectal filling was required and some Centres attempted to address this.

RTIG and publications

RT01 provided a unique opportunity to compare technique related accuracy across Centres, fortuitous given that this was not an aim of the trial. My involvement and discussion in the QA group led to participants' RT01 practice methods being analysed against trial accuracy data to inform evidence-based recommendations for best practice (7). An RTIG questionnaire was devised for all participants on their current RT01 practice details and changes made for the trial. Analysis of returns showed that during preparation to enter patients, or afterwards, as a result of the trial documentation and/or RTIG discussion, all Centres made changes to methods aimed at improving accuracy and up to 80% made changes to any one of:

- couch/surface rigidity
- patient positioning methods
- iso-centre setting methods
- imaging related practice
- patient compliance with bladder and rectal filling instructions

Cross analysis of accuracy data with the RTIG data showed correlation between accuracy and practice methods. In three Centres accuracy was inferior in one axis, with the occurrence of larger discrepancies, which related to a detail of their set-up methods being contrary to best practice. One used an inadequate

treatment couch surface and another used anterior SSD rather than HAC to set isocentre height, both resulting in decreased accuracy in the AP axis.

Recommendations included:

- Reproducibility: comfortable bladder, whole-body patient position and supports; align lateral tattoos in both longitudinal and vertical directions
- Set isocentre using: anterior tattoo for the lateral direction, lateral tattoos for the superior/inferior direction; solid/carbon couch top; HAC as the reference measurement, not the anterior SSD (Creutzberg et al. 1996, Greer et al. 1998, Hurkmans et al. 2001) nor couch height readout alone

A 5mm tolerance margin was allowed, displacements ≤ 3 mm were acceptable. Overall isocentre positioning was within 5mm in every direction on 83% of 7535 fractions imaged. Of 695 patients, 81% had at least one ≥ 3 mm displacement and 63% had at least one ≥ 5 mm displacement (8). Beam modification with MLC rather than blocks, and using PI software rather than film, were associated with fewer displacements, evidencing the effect of appropriately used technology on accuracy. Perera et al. (1999) reported difficulty in identifying 5mm errors using manual methods. Patient set-up uncertainties contributed the largest component of the displacements, not all of which were corrected dependent on correction policies. CFRT decreased side-effects and has become the standard of care (Dearnaley et al. 2007).

3.7 Summary

By dissemination of the Leeds research work and related knowledge, I led the profession into research activity and also influenced:

- radiographer education particularly for those returning to practice
- quality assurance guidelines
- equipment design and QA
- developments in PI treatment verification and decision-making, particularly by radiographers
- clinical trials, resulting in patient position and set-up technique inclusion in protocols and QA.

The RT01 trial QA and RTIG activities led to participants improving practice for pelvic treatments and extending the principles to other body sites, helping the implementation of CFRT in the UK. The two radiographer led publications (7, 8) contributed unique cross-Centre accuracy results related to set-up methods, PI verification and equipment. They showed that considerable learning, preparation time, appropriate technology and user skills and ongoing work are necessary to implement new and complex practice. The Leeds principles incorporated in the trial methods had been widely tested, proven and extended. Other professional issues potentially affecting quality were identified.

CHAPTER 4. FURTHER IMPACTS AND RELATED DEVELOPMENTS

The impact of developments, others use of the work, my own work relating to resource shortages that were perceived to compromise high quality radiotherapy, and revision of the textbook are outlined in this Chapter.

4.1 Use of seminal work by others

Clinical Trials

The principles from (1-6) were used in and built on in the RT01 trial then adopted by all participating Centres.

Methods, reproducibility and patient positioning

Mantle: Plant et al. 1986 used (1) when improving shielding systems, Weltens et al. (1993) used (4) in work on accuracy and dose, Gildersleve et al.(1994b) used (3) concerning para-aortic node error detection, de Geijn et al (1995) used (4) in considering dose under blocks as did Miller et al. (1995) also using (3). Bentel (1996 USA planning textbook) used (3-5) concerning reproducibility, dose planning uncertainties, and skin marks. Breast: Newman et al. (1989, Canada) used (3, 4) in relation to positioning and pulmonary changes after breast radiotherapy; physiotherapists Johnson and Musa (2004) used (11) in patient preparation for radiotherapy.

Portal Imaging

Clinical evidence from (2) was used by authors developing PI (1989-1998) including a 1993 US Patent application and physics book by Thomason (1998). USA/Canadian physics citations include Munro (1995) using (5, 10, 11), Morgan et al. 1998 and AAPM (2001) using (5) as did Shalev (1996). Greer et al. (2008) used (6), as did Wang Jun et al. 2005 (China) and Aksu et al. (2006, Istanbul).

Pelvic accuracy

Authors including: Rabinowitz et al. (1997), Rattray et al. (2008) used (6), Creutzberg used (5, 6, 18) in a PhD thesis (1998) and (5, 6) in a paper (1996), commenting on our improving our methods “use of alignment lasers reduced both the incidence and the maximum value of lateral shift errors”; (Lennernäs et al. 1995) showed accuracy in (6) was superior to other studies reported.

CFRT, IMRT

Relating to skin marking techniques in CFRT, Wurstbauer et al. (2008, Austria) used (5, 6) and Mowbray (2006) used (1). Verhey 1995, McShan et al. 2006, used (5, 6) in planning to account for random geometric uncertainties in IMRT (Ann Arbor, USA), Rudat et al. (1996, Germany) used (5) for CFRT prostate accuracy where Fiorino et al. (1998) used (6), Yan and Lockman (2001, USA), used (3, 4) on the dose consequences of inter-treatment organ and patient geometric variation. Kihlen and Ruden (1989), and Stroom (2000) used (3, 4) in developing safety margins. Weidner et al. (1999 USA) used (6) for pelvic margins, as did Denham et al. (1994 NSW). Boopathy et al. (2010, India) used 3 concerning IMRT.

Quality assurance

High profile QA reports used (5, 6), including Dixon and O'Sullivan (2003, National Cancer Institute of Canada Clinical Trials Group). Radiotherapy QA: time for everyone to take it seriously; Radiotherapy quality assurance in context: The EORTC quality programme in variability during treatment; IPEM report (1999) Physics Aspects of Quality Control in Radiotherapy (Mayles et al.).

Resources

Evidence (18) was used by others in relation to resource pressures, including various RCR reports, Creutzberg et al. 1996 concerning 'radiographers must not be put under time pressure', Delaney et al. (1997, 1999, 2002, 2003 NSW) used (5) in relation to workload and technology.

4.2 Radiographer staffing, increasingly complex practice, accuracy and risk management

Treatment errors resulting in under dosage of the target tissue, including inaccuracy and geographical miss, can arise from inadequate notation, communication, transfer and interpretation of complex treatment data. The potential for such errors is increased when using complex techniques and technology, and under pressured conditions (local study App 11, WHO 2008, RCR 2010). I was invited, with my colleague, to review radiotherapy developments in a new peer reviewed journal (19). Increasingly complex practice using new technology and PI were professionally exciting. However, escalating technology training needs with waiting lists and workload pressures,

staff and equipment shortages, caused concern in managing safe high quality services. Practice developments often lengthen setting-up time and incur extra QA time. A study led by another colleague (18) showed that when radiographers worked under increased time pressure using a complex matched field technique (simulated conditions), accuracy decreased, posing enhanced risks under these conditions.

Risks also arise from lack of staff continuity (thus unfamiliarity with individual patients and their treatment set-up), and sometimes unfamiliarity with the technology. Shortage of radiographers in a Department undermines the ability to arrange staff continuity, and to adequately train staff with different technologies used. Most departments were concerned about the viability and safety of continuous provision of services in the absence of highly specialised more experienced staff (who often returned from maternity leave as part-time employees, leaving services partly covered at best) who are not replaceable by short term appointments. The expertise of such staff is crucial in developing safe and effective practice, using and training a succession of others with new technology and practice to reduce the potential for serious errors, and detecting and acting on issues which could lead to errors (WHO 2008, RCR 2010). A successful new structure in Leeds had an increased number of specialist posts. A Guest Editorial aimed to help others obtain adequate establishments (20). Staffing requirements for a range of highly specialist services inclusive of brachytherapy, research and patient support were described and justified, including allowance for: technology training; CPD; annual, sick, and maternity leave cover. Consultancy roles followed, as the sole investigator into a serious error in a London Centre and to assess radiographer staffing required in a large UK Centre (App. III).

Radiographer shortages led to radiotherapy waiting lists, such that NRAG was created (2004), requiring radiographer staffing recommendations to plan for expanding services, as we recommended in 1996 (19). Frustrated by lack of guidelines, after 10 years of effort (RCR 1998, App. I-III), I designed and analysed a national survey to establish the overall WTE required for managing and delivering high quality radiotherapy services, to the current best practice (23). The outcome was a national staffing formula adaptable for any sized department

(used by NRAG in 2005). This work, undertaken for the UK Radiotherapy Managers' Group (with 42 respondents from two thirds of Centres in England and Wales) underpinned an interim radiographer staffing benchmark (COR 2005). The survey identified many inadequate staff establishments, a 17% vacancy level consistent with findings of Abraham et al. (2003), 4% maternity leave absence, and shortage of radiographers causing daily loss of linac capacity in 43% of the 42 Centres, affecting efficiency and services. Risks associated with inadequate staffing, and workloads safely achievable were discussed.

4.3 Workloads, efficiency and linac capacity available

In Leeds, complexity of treatments due to quality improvements had increased the workload per patient, beyond that which could be accommodated with the current linac and staff capacity, discussed in (2, 5, 19). As Head of Department, with concerns about the resultant unacceptable radiotherapy waiting times, I organised a BIR conference on resources (App. III). The RCR Oncology Dean presented findings to the DOH, i.e. 'A critical shortage of radiotherapy resources developing in the UK, with consequences for cancer services'. I was involved in initiating, designing, and analysing an equipment, staffing and workload UK survey (1992). Results were presented to a 1994 MRC workshop and circulated to all Centres in 1995 (App. I-III). A second questionnaire (1997) revealed variable equipment distribution and increases in workload over 5 years (19) outpacing that of resources, with Radiographer shortages even using the old COR (1979) guidelines (RCR 1998).

When seeking extra linacs locally, I had proposed a formula to Dr Ash (a Leeds Oncologist who became RCR Dean) to quantify the number of linacs (of a given capacity) required, based on cancer incidence, indicative referral rates and treatment workloads per referral (as fractions/exposures), per million population served (19). Subsequently, this became the basis for determining linac complements nationally RCR (1998), DOH (2000), Williams and Drinkwater (2009). The Dean (later RCR President) set up radiotherapy waiting time and equipment audits, (RCR 1997, 1998) and pressured Ministers to persuade Government that improvement of the national equipment infrastructure was required. The RCR 1992-7 survey data was used by Cottier (DOH 1999) to

identify departments requiring more linacs (and replacements) to a norm of 4 linacs/million for their catchment populations (approx. cost per linac = £800,000). More than 50 machines were supplied initially from treasury funding. Later the complement of equipment in many Centres was raised further to recommendations in RCR (2000) which reflected discussion in (19).

Radiographer shortages prevented extra linacs being fully utilised. In Leeds we strived to use radiographer time efficiently, whilst recognising essentials for minimising risks using computerised technology, such as technology training and appropriate data entry and set-up conditions (12-14, 18-20, 23, 24 pp.295,305, MDA 1998, WHO 2008, RCR 2010). Australian experts on measuring radiotherapy productivity using Basic Treatment (time) Equivalent, approached me to lead a study (21), in which the effects of practice, staffing and technology on treatment fraction times in Leeds, were quantified and compared with NSW Australia findings (Delaney et al. 1997). We looked for the factors which increased fraction times, so potentially impacted on accuracy and waiting times. A shorter mean fraction time was identified when using MLC and non-operational time was 50% of that in NSW. The study quantified our high productivity and supporting a strong case for more MLC machines.

A study by an SHU colleague, involving my service knowledge, examined which breast cancer patients benefited from complex radiotherapy techniques, such as IMRT, with possible consequences for waiting times under limited resource availability (22). The role of patient positioning and treatment accuracy in limiting morbidity (Canney et al. 1999), potential technically related risks (Kron, 2002) and benefits, were balanced against the required clinical outcomes for different subgroups of patients. This identified that only a small subset of women at greatest risk from normal tissue morbidity or reduced cosmesis (Coles et al. 2005) require techniques such as CFRT or IMRT.

4.4 Radiotherapy textbook

Radiographers needed a relevant source of quality-related information for reference and training others. Knowledge and principles from the Leeds research (1-6) supported by relevant literature, were incorporated into a textbook 'Radiotherapy: Principles to Practice. A Practical Manual for Quality in

Treatment Delivery' First Edition, by SE Griffiths and C Short, (Longman UK 1994), for which I was project and design lead, authoring chapters 1, 6, 12-24. My colleague Chris Short, an expert in the clinical use of computerised treatment technology, wrote the technology chapters (2-4, 7-10).

Uniqueness

The book's unique structure and content were intended as a learning resource and practical working manual on quality assurance principles, grounded on the evidence-base, and relating quality theory to safe practice for each topic. It was primarily to inform radiographers and students on aspects of practice not available in other textbooks. These, e.g. Dobbs et al (1985), written primarily for medical and physics trainees in radiotherapy, covered oncology, disease management and radiotherapy planning, radiation physics, field arrangements and dosimetry. Our book provided a comprehensive foundation in all radiotherapy delivery-related topics, highlighting technique informed by Leeds research. Principles underpinning safe planning and delivery processes, from relevant radiobiology and dosimetry, equipment design features and usage, data-checking systems, reproducibility and accuracy monitoring by PI, to staffing and service management were included. To our knowledge this was the first and only available text at that date illustrating setting-up techniques with underlying theory and principles. Differing techniques used in various body sites were compared and evaluated. Other topics were researched from textbooks, attendance at conferences and by assessing a wide range of equipment from different manufacturers being used in clinical practice at other Centres. Much information was thus leading edge. New and developments aspects of equipment, PI, conformal and stereo-tactic techniques were included to introduce readers to the developments in treatment planning and technology on the horizon. (Later a book for USA radiographers, Washington and Leaver (2009), covered reproducibility and set-up accuracy).

Impact of the first edition

On publication the impact was worldwide, quickly selling over 1500 copies, necessitating a second print run (despite the limited market in this small profession). Universities adopted the book as standard reading for student radiographers. It was used by the RCR for radiation oncologist training in the UK

and abroad, and by some specialist nurses. Enquiries came from medical staff, especially in the Indian subcontinent and China, some asking if a translated version was available.

The second edition

Although the principles still held, within a decade the rapid revolution in technology and practice, required a revision agreed with my previous co-author, who was no longer available to assist. Following retirement, as an Honorary Researcher at St James's Institute of Oncology and Visiting Professor at Sheffield Hallam University, I revised the book with recently extended accuracy principles and knowledge from RT01. I revisited the original text, researching, updating and restructuring to include a new section on the much expanded topic of imaging and clinical decision-making (24). Technology driven treatment delivery innovations such as Tomotherapy and stereotactic systems using robotically controlled equipment movements and image feedback, for any body site, were being introduced. Applications of these are described and dynamic correction of beam delivery alignment on target tissue, despite organ movement, demonstrated on an integral CD. Collaboration with equipment experts was necessary. As a result of longstanding relationships, manufacturers willingly supplied information, illustrations, and text corrections, and part-sponsored production, as did the national (radiographer) Recruitment Retention and Return Project. The original approach, confining the content to subjects directly concerned with safety and quality assurance of radiotherapy delivery, including equipment design requirements, data-checking systems, service management, training and staffing, was used. These topics feature in recent radiotherapy risk management reports (WHO 2008, RCR 2010), which recognise that increasing complexity and new technology bring their own safety risks.

The published review

This second edition (2008) was reviewed by Bridge, SHU (App. V), who commented also on the first edition, 'It has long been valued as one of the few hallowed standard texts in radiotherapy with its clear explanations and wide-ranging discussion of quality issues in practice.' 'In summary, the revised second edition should maintain its status as a well-respected and valuable text.

The updates and restructuring align it strongly with trends in current practice and it is to be recommended as essential reading for anyone striving to improve quality of treatment delivery'

4.5 Summary

The earliest work is still widely quoted internationally, with over 100 citations by others, many in prestigious groups and organisations, and national/international guidelines. Significant impact was made on national initiatives for radiotherapy staff and equipment provision. The research informed a textbook.

Key aspects of the substantial body of work submitted have been reviewed in this thesis. The research was undertaken while in employment as a clinical therapy radiographer and, through a long term record of quantitative studies evidencing accuracy improvements and quality issues, contributions to peer-reviewed publications, books, and authorship of a textbook have been made.

5.1 Culture change resulting from the work

Development and QA of radiotherapy and technology used were domains of medical physicists and oncologists. The research challenged a number of practices. I was able to demonstrate issues to these disciplines, enabling critical practice changes and awareness of geometric accuracy achievable. I also influenced working practice by colleagues, and led the profession into research and national multi-disciplinary group work. The programme of research identified and implemented improvements throughout the radiotherapy process, leading to enduring multi-disciplinary practice changes (and contributing to the clinical management of lymphoma). This and successful input to national collaborative groups over 20 years helped to develop the current multi-disciplinary approach to clinical trial QA, designing and developing new technical practice, and allowing inter-professional challenge of assumptions (RCR 2010). I was able to influence aspects of technology QA and design, leading to equipment modification.

5.2 Accuracy improvements

The outcomes established and addressed the origins of treatment inaccuracies. The magnitude and frequency of errors arising at the start of treatment, and random errors, were greatly reduced. Accuracy achieved for the pelvis was superior to others results, and within contemporary expectations.

5.3 Others have recognised the work to be significant, as follows:

- The ESTRO-Calergo Award, a European prize offered for the first time for research leading to improvements in the safety of radiotherapy received for this research programme (awarded 1991)
- Fellowship of the COR for research contributions to the profession (awarded 1991)

- Honorary membership of the RCR for contributions to Oncology (awarded 1994)
- Invited to Founder Membership of the governing body of Cancer Research UK (the only radiographer) from 2002

5.4 National multi-disciplinary activities resulting from the research:

- Invited to wide dissemination of seminal work at high profile multi-disciplinary conferences (App.II), including: 50th Anniversary of Megavoltage (1987), ESTRO (1991), BIR (1991, 1992 and review lecture on quality control (1994).
- Invited membership of BIR Oncology Committee (first radiographer)
- Input and involvement sought in the two first clinical research trials to consider treatment delivery QA. Trial QA documents incorporated Principles from the research.

5.5 Summary

The work submitted introduced evidence-based new practices locally, which improved accuracy and spread nationally and internationally, impacting on execution of clinical trials. RT01 trial activities led to participants improving practice for pelvic treatments, and extending the principles to other body sites, helping the implementation of CFRT in the UK. The principles developed in the work, which is still widely cited by all involved disciplines, critically underpin current high quality treatment delivery using small volume, high-dose radiotherapy internationally. The research helped to drive development of aspects of technology, PI verification and on- treatment decision-making by radiographers, quality guidelines used in contemporary radiotherapy, the clinical management of lymphoma, creation of radiographer staffing guidelines, and contributed to improved national radiotherapy resourcing. All these have recently been linked with quality and safety in radiotherapy by WHO (2008) and RCR (2010).

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Royal College of Radiologists, Institute of Physical Sciences in Medicine. College of Radiographers (2008). On target: Ensuring geometric accuracy in radiotherapy. RCR BFCO(08)5

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* denotes first author or major/significant contribution

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* 1994 Radiotherapy : Principles to practice. A practical manual for quality in treatment delivery. Griffiths SE, Short CA. Churchill Livingstone Edinburgh. reprinted 1995. ISBN 0-443-04783-9. Copyright now with authors, revision invited. Personal contributions : Overall project management and principal author, writing 17 of 23 chapters.

* 1997 Section 2.2 The radiographers view. In- The design of radiotherapy treatment room facilities. Eds Stedeford B, Morgan HM, Mayles WPM (IPEM Report 75): The Institute of Physics and Engineering in Medicine. York.

* 2001 Chapter 6 - Safe Practice and Prevention of accidents in afterloading. Flynn A, Griffiths SE, Joslin CAJ In- Safe practice and prevention of accidents in afterloading brachytherapy Eds Flynn A, Hall E J, Joslin CAJ Arnold

* 2006 The story of a Cancer Hospital – Cookridge Hospital 1972-2006. 50th Anniversary of Radiotherapy. Project lead, design and writer, editorial group chair. In press (University of Leeds print services). © Leeds Teaching Hospitals NHS Trust.

* 2008 Radiotherapy : Principles to practice. A practical manual for quality in treatment delivery. Second edition. Griffiths SE. University of Leeds print services © Leeds Teaching Hospitals NHS Trust.

PEER REVIEWED PAPERS

* 1985 The reproducibility of large lead protected radiotherapy fields to the abdomen and pelvis. Griffiths SE, Pearcey RG. Radiography 51.247-250

* 1985 The impact of treatment errors on post operative radiotherapy for testicular tumours. Pearcey RG, Griffiths SE BJR 58.1003-1005.

* 1986 The daily reproducibility of large complex-shaped radiotherapy fields to the thorax and neck. Griffiths SE, Pearcey RG Clin Radiol 3.39-41

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* 1987 Quality control in radiotherapy : the reduction of field placement errors. Griffiths SE, Pearcey RG, Thorogood J. Int J Radn Oncol Biol Phys 13: 1583 - 1588

- * 1991 Quality control in radiotherapy during pelvic irradiation. Griffiths SE, Khoury GG, Eddy A. Radiotherapy and Oncology 20: 203 – 206 (European award)
- * 1995 Increasing the workspeed of radiographers: the effect on the accuracy of a set-up of a complex-shaped cranial field, part of a matched cranio-spinal junction. Probst H, Griffiths SE. Radiother Oncol 38:241-245
- * 1996 Radiotherapy : Developments, contradictions and dilemmas. Short CA, Griffiths SE. Invited Review article. Radiography (new peer reviewed journal) 2,177-189.
- * 1999 Therapy Radiographer Staffing for the treatment and care of cancer patients. Guest Editorial. Sue Griffiths Journal of Radiotherapy in Practice. Vol 1 issue 4 p 159-232
- * 2003 An assessment of Basic Treatment Equivalent at Cookridge Hospital. Griffiths S¹, Delaney G², Jalaludin B³. Clinical Oncology (2003)14:399-405
1Cookridge Hospital UK, 2 Collaboration for Cancer Outcomes Research and Evaluation University of New South Wales, 3 Liverpool Hospital, NSW.
- * 2006 Moving to a High-tech Approach to the Irradiation of Early Breast Cancer: Is it possible to Balance Efficacy, Morbidity and Resource Use? Probst H, Griffiths S. Clin Onc (2006) 18: 268-275
- * 2006 Radiographer roles and risk management in Radiotherapy. Griffiths S, Craig C, Abraham M. of Radiotherapy in Practice. 5: 137-146
- * Retaining Therapy Radiographers: What's so special about us? Probst H and Griffiths S. Journal of Radiotherapy in Practice 6:21:32 2008
- * Job satisfaction of therapy radiographers in the UK: Results of a phase I qualitative study Probst H, Griffiths S. Radiography. Available online 2 April 2008

PEER REVIEWED PUBLICATIONS, NATIONAL GUIDELINES, TRIAL PROTOCOLS ETC. AS WORKING GROUP MEMBER

Royal College of Radiologists

- * 1992/3 Equipment, workload and staffing in the UK 1992/3 national survey - results presented at an MRC meeting in 1994 with Dr Jill Bullimore and circulated to all radiotherapy departments in 1995, on behalf of the RCR and COR
- * 1996 Guidelines for the Management of the Unsheduled Interruption or Prolongation of a Radical Course of Radiotherapy. RCR ref No BFCO(96)4 (also later revision)
- * 1997 Extending the Working Day for Delivery of Radiotherapy. RCR BFCO(97)3
- 1998 A National Audit of Waiting Times for Radiotherapy. RCR BFCO(98)1 (acknowledged contributor)

* 1998 Equipment, workload and staffing in the UK 1992-1997 RCR, BFCO(98)2. Analysed with the RCR and Dean Dr Dan Ash. (acknowledged contributor)

*1999. Guidelines for external beam radiotherapy. Writer/lead for Treatment Delivery Section 3, also Appendix 4: Reproducibility in Treatment Delivery. RCR Radiotherapy Clinical Oncology Information Network. Clinical Oncology 11:S148-S171

*2004 Guidance on the Development and Management of Devolved radiotherapy services. BFCO(04)1(acknowledged contributor)

2008 RCR, IPEM, COR On target: Ensuring geometric accuracy in radiotherapy. RCR (BFCO(08)5
(sole reviewer)

Commission Of The European Union

*28. 1995 A Core Curriculum for first level education programmes in radiotherapy technology. First edition. Public Health - The Europe Against Cancer Programme

Medical Research Council

1996 Trial Protocol and Quality assurance protocol for Conformal Radiotherapy Studies, Radiotherapy working party Quality Assurance Group (Chair Dr Anna Gregor)

RT01 trial -

*1998 MRC Trial management Group. RT01 A randomised trial of high-dose therapy in localised cancer of the prostate using conformal radiotherapy techniques. Clinical protocol version 1 (including QA).

*1997/8 RT01 Planning and Treatment delivery : Local Work Instructions. RT01 trial specimen process document for MRC Trial Quality Assurance Group (Led multi-disciplinary work at Cookridge to produce this description of our treatment processes, with a similar document produced by the Royal Marsden Hospital)– distributed with Trial Protocol as good practice examples for participants to adopt/adapt.

* 1997/8 RT01 Physics questionnaire produced by the MRC RT01 Quality Assurance Group – large document distributed for participating centres to complete. Major input on set-up sections.

* MRC Radiotherapy Working Group RTO1 (2000). A randomised trial of high-dose therapy in localised cancer of the prostate using conformal radiotherapy techniques. Clinical Protocol version 2.

* 2004 Mayles WPM, Moore AR, Aird EGA, Bidmead AM, Dearnaley DP, Griffiths SE, Stephens RJ, Warrington AP on behalf of all the RT01 contributors. Questionnaire based quality assurance for the RT01 trial of dose escalation in conformal radiotherapy for prostate cancer (Medical Research Council ISRCTN 47772397). Radiother Oncol 73 :199-207

* 2004 Implementing the UK Medical Research Council (MRC) RT01 trial (ISRCTN 47772397): Methods and practicalities of a randomised controlled trial of conformal radiotherapy in men with localised prostate cancer. Sydes MR, Stephens RJ, Moore AR, Aird EGA, Bidmead AM, Fallowfield LJ, Graham J, Griffiths S, Mayles WPM, McGuire A, Stanley S, Dearnaley DP, and the RT01 collaborators. *Radiother Oncol* 72: 199-213

* 2005 Griffiths-S, Stanley-S, Sydes M, and RT01 Radiographers Group on behalf of all the RT01 Collaborators Recommendations on best practice for radiographer set-up of conformal radiotherapy treatment for patients with prostate cancer: experience developed during the MRC RT01 trial (ISRCTN 47772397) *J Radiother in Pract* 4: 2

2008 Accuracy and reproducibility of Conformal Radiotherapy using data from a randomised controlled trial of conformal radiotherapy in prostate cancer (MRC RT01, ISRCTN47772397). S Stanley, S Griffiths, MR Sydes, R Moore, I Syndikus, DP Dearnaley and the RT01 Radiographers Group on behalf of all the RT01 Collaborators. *Clin Onc* 20:582-590 2008

Institute of Cancer Research , START Trial Management Group -

* 1998 UKCCR Standardisation of Breast Radiotherapy (START) Trial Final Protocol

* 1999 Standardisation of Breast Radiotherapy (START) Trial. *Clin Onc* 11:145-147.

2000 Venables K, Winfield E, Deighton A, Aird E, Hoskin P, on behalf of the START Trial Management Group. Breast Radiotherapy phantom design for the START Trial. *BJR* 73:1313-1316.

2001 Venables K, Winfield E, Deighton A, Aird E, Hoskin P, on behalf of the START Trial Management Group. A Survey of radiotherapy quality of control practice in the United Kingdom for the START Trial. *Radiother Oncology*. 60: 311-318.

2001 Venables K, Winfield E, Deighton A, Aird E, Hoskin P, on behalf of the START Trial Management Group. The START Trial measurements in semi-anatomical breast and chest wall phantoms. *Phys Med Biol* 46: 1937-1948.

2002 Winfield E, Deighton A, Venables K, Hoskin PJ, Aird EGA, on behalf of the START Trial Working Party. Survey of UK breast radiotherapy techniques: background prior to the introduction of the quality assurance programme for the START trial in breast cancer. *Clin Onc* 14: 267-271.

OTHER PUBLICATIONS

* 1986 Reproducibility in radiotherapy. Griffiths S E *Radiography* 52: 167 - 169

* 1989 Hit or Miss - is perfection achievable in radiotherapy? Griffiths S E *Radiography* 56: 17

* 1990 Radiotherapy quality control: portal and verification films. Griffiths S E *Radiography* 56: 17

- * 1996 Second Century Radiotherapy. Griffiths S. Synergy, March 1996 p39-40
- * 1999 Quality management systems in use in oncology Centres in the UK. Survey and discussion for N&Y RHA Regional Clinical Governance Advisory Group, and DoH Clinical Governance Websites.
- *1999 Quality systems in radiotherapy and Clinical Governance. Griffiths S. Review published on DoH Clinical Governance website.
- * 2003 First Leeds trainee 'assistants' on track to qualify in 2005 as radiotherapists Griffiths S. Synergy News p5Jan
- * 2003 COR A curriculum Framework for Radiography.

ABSTRACTS etc.

*1989 Griffiths SE, Khoury GG Pelvic field irradiation: An investigation of accuracy of treatment delivery. British Oncological Association Annual Meeting, York Poster

*1992 Griffiths SE 'Quality Control: What is possible?' Abstract. Proceedings, Radiology and Oncology '92. BJR

2002 Dearnaley DP, Aird E, Bidmead AM, Fallowfield LJ, Graham J, Griffiths SE, Huddart RA, Love K, McGuire A, Mayles W, Moore R, Naylor S, Sydes M, Stephens RJ, Syndikus I. High-dose conformal radiotherapy (RT) in localised prostate cancer :The MRC RT01 randomised trial (ISRCTN 47772397). Pro Am Soc Clinical Oncology 2002: 21:193a, Abstract 769.

*2003 Griffiths S, Stanley S, Cassapi L, and RT01 Radiographers Group on behalf of all the RT01 Collaborators MRC RT01 trial ISRTCTN (47772397) – Towards consensus on prostate set-up Poster. UKRO Conference April 2003 Clin Onc vol 15: 2, pS26 abstract P20 presentation, First JRP conference, SHU. Abstract

*2003 Griffiths S, Stanley S, Cassapi L, and RT01 Radiography Trial Implementation Group on behalf of all RT01 Collaborators.MRC RT01 trial (ISRTCTN 47772397) quality assurance and radiographer trial implementation group: Prostate set-up best practice development Conference presentation, First JRP conference, SHU. J Radiother in Pract 3: 3:160-161. Abstract

*2005 Griffiths S, Stanley S, Delaney G, Shafiq J, Jalaludin B. A repeat study of radiotherapy productivity using the Basic Treatment Equivalent at Cookridge Hospital, Leeds. Poster UKRO3 Abstract Clin Onc 17:S33

*2005 Griffiths S on behalf of contributing radiotherapy service managers. Radiotherapy staffing and services survey for 2003/2004. Clin Onc 17: S15. 3rd UK Radiation Oncology Conference UKRO3

*2005 Griffiths S, Stanley S, Delaney G, Shafiq J, Jalaludin B. A second study of radiotherapy productivity, using the basic treatment equivalent, at Cookridge

Hospital, Leeds. Clin Onc 17: Supplement 1. 3rd UK Radiation Oncology Conference UKRO

*2005 Griffiths, S on behalf of contributing radiotherapy service managers. Staffing establishments and the 4 tier structure. Second JRP conference, SHU. J Radiother in Pract, vol 4. Abstract

*2006 Griffiths S, Stanley S, Roberts N and Delaney G. The effect of auto set on fraction time. Abstract for Radiotherapy in Practice 3, J Radiother in Pract Vol 5

*2007 Putting research strategy into practice. Sue Griffiths, Angie Craig. Abstract COR conference proceedings Feb 2007.

PUBLICATIONS IN PREPARATION in 2010

The Evolution of Radiotherapy Techniques Griffiths S. Write up of inaugural lecture topic.

Burnout in Therapy Radiographers Heidi Probst¹, Cathy Hill¹, Sue Griffiths^{2, 1} Sheffield Hallam University, ² St James's Institute of Oncology, Leeds

SIGNIFICANT INTERNAL REPORTS TO MANAGERS AT COOKRIDGE HOSPITAL

1987 Case of need for radiotherapy staff and facilities approx 10,000 words

1988 Factors decreasing patient throughput on linacs – report sent to DHSS by hospital management.

1989-90 Major equipment (linac) evaluations on behalf of radiographers (approx 6500 words)

1990 Work analysis document for cost and contracting for external beam radiotherapy at Cookridge, the most sophisticated radiotherapy model successfully used from the start of contracting (in use until recently, closely mirrors HRG banding), developed with colleague Chris Short.

During head of department role -

1995 Analysis of the effect of technology on complexity, resource use, and work per referral.

1995 Internal report on service problems, eventually leading to securing extra revenue of £0.65 million per annum to support service quality and robustness (approx. 7,000 words)

1995/6 Devised new staffing structures for Radiotherapy, achieved locally via above funding.

2004 Analysis of the effect of complexity, work per referral on resource use and capacity at Cookridge, with implications for waiting times, for the Management team.

Appendix 11. DISSEMINATION BY PRESENTATION

INVITED CONFERENCE PRESENTATIONS, SEMINARS AND LECTURES OF NOTE

International

1987 50th Anniversary of Megavoltage Conference, London. Field placement errors and their minimisation

1991 University Hospital St. Rafael, Leuven, Belgium. The reduction of errors in pelvic radiotherapy (The work for which the Calergo prize was awarded)

1991 European Society for Therapeutic Radiology and Oncology second teaching course for technologists, Granada. Reproducibility in daily practice - a literature review.

1992 BIR, London. Megavoltage Portal Imaging Meeting. Assessment and reduction of errors.

1993 RCR, London. International conference on QA in Radiotherapy. QA in treatment delivery.

National

1985 COR Teachers and Superintendents Conference, Reproducibility in Radiotherapy

1988 COR Annual Conference, Scarborough. Hit or Miss?

1988 IPSM - Quality Assurance Seminar, Royal Marsden Hospital, London. The reduction of field placement errors.

1990 Royal Marsden Hospital, London. IPSM meeting on treatment facilities design. What radiographers want from radiotherapy treatment facilities.

1990 COR Radiotherapy Conference, York. Setting up a technical quality assurance programme.

1991 RAD Society meeting, University of Leeds. Reproducibility of set-up and accuracy of radiotherapy treatments.

1991 BIR, London The role of brachytherapy in cancer management. The dose rate dilemma - delivering the treatment.

1992 BIR Review lecture at Radiology and Oncology '92. 'Quality Control - What is possible?'

1994 BIR, London. The management of clinical workload and resources in Radiotherapy. London. Meeting organiser/presenter. In the balance - demands and resources and the future of Radiotherapy.

1994 RCR, London. Information needs and benefits in Clinical Oncology. Issues and potential benefits for Radiographers.

1994 University of Edinburgh Radiobiology (closed) Workshop on accelerated fractionation. Accelerated Fractionation : Practicalities and Economics.

1995 COR radiotherapy meeting. The impact of new technology on Brachytherapy treatment.

1995 MRC open meeting of radiotherapy working party, London

1. Results of the radiotherapy workload and equipment survey 1992/3 (with Dr Jill Bullimore)

2. Overview of Research activity at Cookridge Hospital

1997 RCR Annual Meeting, London. Staffing and workload factors in Radiotherapy.

1997 BIR Radiation Protection Meeting, London. Local Rules in radiotherapy.

2002 National Cancer Research Institute Radiotherapy and Lymphoma group – presentation and input on quality assurance in radiotherapy for Hodgkins disease.

2007 COR Radiotherapy weekend conference. Putting research strategy into practice.

2009 The Evolution of Radiotherapy Techniques. Inaugural lecture SHU

Presentations by submission

2001 Radiotherapy errors/incidents : trends over 8 years 1992-2000
Presentation UKRO 1 Griffiths S

2003 Modernising funding for radiography education and training: Accessing resources. Griffiths S. COR Radiotherapy Conference

2003 S Griffiths, G Delaney, B Jalaludin. A study of radiotherapy workload and staffing using the basic treatment equivalent, at Cookridge Hospital, Leeds.
Radiographer Conference

2004 Staffing and Services survey, results, implications and possible ways forward. Sue Griffiths on behalf of all contributors. National Radiotherapy managers meeting, Manchester

2004 National radiotherapy distance learning programme development.
Radiotherapy managers meeting, Manchester

2005 Radiotherapy staffing and services survey for 2003/2004. Griffiths, S on behalf of contributing radiotherapy service managers. 3rd UK Radiation Oncology Conference UKRO3

2005 A second study of radiotherapy productivity, using the basic treatment equivalent, at Cookridge Hospital, Leeds. Griffiths S, Stanley S, Delaney G, Shafiq J, Jalaludin B 3rd UKRO Conference

2005 Staffing establishments and the 4 tier structure. Second JRP conference, SHU

2006 The effect of auto set on fraction time. Griffiths S, Stanley S, Roberts N and Delaney G. Radiotherapy in Practice 3, SHU

2007 Putting research strategy into practice. Presented Feb 2007 COR conference.

2007 The role of the Radiographer: Radiographer consensus in RT01 and beyond. Closing MRC RT01 Trial meeting, London.

Locally organised conferences or teaching courses, by invitation

1984 University of Leeds, Dept. of Radiotherapy (with Dr Pearcey) Accuracy and Reproducibility

1986, 1987 Hogarth School of Radiotherapy, Nottingham. Accuracy factors in technical practice

1988 The Princess Royal Hospital, Hull. Technical Quality Assurance

1989 COR, Yorks. Regional Branch Weekend Meeting. Advances in photon therapy

1989, 90 Leicester School of Radiography HDCR course. Technical Accuracy and verification films

1989, 1991 Teaching lectures on Fellowship of the RCR course (medical staff) at Cookridge Hospital.

1992 Cancer Research Campaign Trials Unit, Birmingham Oncology Centre. Accuracy in radiotherapy.

1996 University of Leeds, Nuffield Centre MA course. Radiotherapy Service Infrastructure for the catchment population.

1997 University of Leeds. Patient accuracy factors in radiotherapy. (with Heidi Probst)

1997, 1998 Chair/session chair. Radiotherapy Conference. Cookridge Hospital, Leeds.

1999 Accrediting work-based learning programmes at Masters level. SHU School of Healthcare Studies

1999 Equipment, staffing and workload and the recent RCR report on this. MSc programme, SHU.

Appendix 111.

INVOLVEMENT IN MULTI-DISCIPLINARY NATIONAL COLLABORATIVE GROUPS

1. INVITED ROLES ON RESEARCH BODIES etc. AS THE FIRST INVITED RADIOGRAPHER

Institute of Cancer Research, Clinical Trials and Statistics Unit (ICRF) 1995-2001 Member of Protocol Writing Group for UKCCR Standardisation of Breast Radiotherapy (START), and trial management group. (Principal investigator, Dr J Yarnold, Clinical Oncologist, RMH)

Medical Research Council:

1995 Member of Radiotherapy Working Party Steering Group for the MRC Cancer Therapy Committee (Chair Dr Anna Gregor) then 1997-1998 The radiographer member of the MRC Radiotherapy Planning Group and Member of MRC trial management Group for Radiotherapy (1998)

1997-2007 MRC RT01 Trial, Chair Dr David Dearnaley, Clinical Oncologist Royal Marsden Hospital:

Member of Trial Management and QA Groups from the outset, later the trial publications group.

Leading/chairing work of MRC RTO1 Radiographer Trial Implementation Group developing best practice through to publications on radiography aspects of the trial in 2005/6

2. OTHER INVITED MULTI-DISCIPLINARY NATIONAL ROLES

British Institute of Radiology

1990-1994 First radiographer member of Radiation Oncology Committee, BIR. Initiated and organised The management of clinical workload and resources in Radiotherapy (1994) RCR Dean took findings (a critical shortage of resources developing in the UK with consequences for cancer services) to DOH.

1995-8 Member of Editorial Board for British Journal of Radiology (BJR), first radiographer member.

The Royal College Of Radiologists

1995/6 Sole radiographer member of working group for producing Guidelines for the Management of the Unscheduled Interruption or Prolongation of a Radical Course of Radiotherapy.

2007 Expert (sole) reviewer for RCR, IPEM, COR (1998) On target: Ensuring geometric accuracy in radiotherapy. RCR (BFCO(08)5

Cancer Research UK

2002/3-present Invited founder member of 80-100 person governing body

3. INVITED ADVISORY ROLES/CONSULTANCY as SINGLE INVESTIGATOR/ RADIOGRAPHER

1994 Input to a closed workshop with various UK Oncologists and Radiobiologists on Accelerated fractionation in radical radiotherapy. Chair Professor W Duncan (University of Edinburgh)

1998 Sole investigator for the multi-disciplinary team, following a serious radiotherapy accident at a London radiotherapy centre. Report and recommendations submitted to Directorate Manager.

1999 Radiography staffing review for Clatterbridge Oncology Centre, report submitted to assistant CEO.

4. INVITED ROLES AS A RADIOTHERAPY CLINICAL EXPERT

The Royal College Of Radiologists

1992-5 Working group developing Health Resource Groupings (HRGs), for radiotherapy contracting.

1993 - 1998 Member of national working party on equipment, staffing and workload in radiotherapy led by RCR with COR. (presented 1992/3 survey results to an open MRC workshop in 1994 and circulated to all radiotherapy departments in 1995, with Dr Jill Bullimore (Dean for Faculty of Oncology)).

1997 Design of 2nd questionnaire, continued involvement in analysis and document production with Dr Dan Ash. This (and a radiotherapy waiting time audit) persuaded government that national equipment radiotherapy infrastructure improvement was required. The RCR data informed the DOH (Cottier) data used to identify departments to be given linacs, using treasury money (linac =£800,000), 50+ linacs supplied initially, later raising linac, CT scanners, and planning equipment to new recommendations.

1995/9 Member of the Clinical Oncology Information Network (COIN) group writing generic external beam radiotherapy guidelines. Section lead writing radiotherapy treatment delivery section. (Chair Dr Anna Gregor, Dept. of Clinical Oncology, University of Edinburgh, now CMO for Scotland)

Appendix IV. RADIOGRAPHER EDUCATION INITIATIVES AND INVOLVEMENTS

PERSONALLY LED INNOVATIONS

1989 Design, co-ordination and delivery of Radiographer refresher course (documented in three volumes) at Cookridge, updated and repeated in 1990. Part of the project work for the award of BEd.

1997/8 Gained accreditation of 3 work-based in-house Masters modular course units as Course Leader (with 3 unit leaders including Heidi Probst) with SHU. The first such accredited course in the UK, with the SHU Outreach Centre, now part of the advanced practice education framework.

2000 Proposed a clinical lecturer post to the University of Leeds funded and evaluated by West Yorkshire Workforce Development Confederation (WYWDC) to support students and Radiotherapy Degree delivery leading to funding for appointment of Practice Development Facilitators for SHU within the new education contract awarded in 2002.

2001/2 Initiated the 'earn and learn' student recruitment scheme aiming to ensure SHU places were filled, necessary to staff the expanding service in Leeds. Realised the potential for recruiting mature entrants changing careers, already living in/committed to Leeds, with contractual requirement to work at Cookridge once qualified. Employed trainees needing financial support. Secured funding (approx. £14,000 per student per year). First cohort qualified in 2005 and employed. Good retention achieved.

2000 Presented the therapy radiography case at a Northern & Yorkshire (N&Y) and Trent Education Consortia (RHA) conference 'A strategy for education and Training in Therapeutic Radiography', NHS executive in attendance. Aim to inform on the key role played by therapy radiographers in curative cancer treatment, the impact of critical shortages on cancer waiting times, and to bring pressure for action, resulting in an increased number of commissions for the Region.

2002/3 Gained £15,000 funding for a student e-learning suite with PCs at Cookridge, then adopted by other centres. Also gained student and tutor suite and facilities in the St James's Oncology building.

2003 Developed an NVQ facilitator post for skills enhancement/accreditation for radiotherapy helpers, gained £12,000 WYWDC funding. Postholder highly successful, gaining assessor status in 6 months and assisting 20 helpers towards NVQ level 3, post extended and later funded by the Trust NVQ centre from 2006. Helpers able to train to assistant radiotherapist level, via SHU work based learning course.

2004 Previously developed a national Open Learning Oncology framework proposed to the Open University (not taken up for logistical reasons), but from the concept developed proposal for a national distance learning Radiotherapy programme, for returners and professional updating, with SHU as partner. Undertook national survey on returner training needs to support this proposal,

gaining top-sliced national WDC funding (£150,000) for a high calibre project manager. Project had COR approval and links to the national Radiography Recruitment, Retention and Return project, and resulted in SHU course from September 2005 meeting the target of 10 students in the first year. The project funds supported the course in its' first (and second) year.

EXPERT/ADVISORY ROLES

1992 - 1994 Member of the European Radiotherapy Technologist Education Development Group, in addition to two statutory UK education members, for production of the first European Core Curriculum.

2001 Invited to lead radiographer input to contract review of radiotherapy education, by the N & Y RHA education lead. Worked with WYWDC in the process including development of the specification for the education provision with the WYWDC lead. Key roles included leading radiography input, input to the RHA on education and student recruitment issues for radiotherapy, working with the RHA. SHU gained the contract for Radiotherapy education, uniquely including all undergraduate routes and postgraduate education. The resulting increased student intake across the region with all commissioned places filled (hitherto not the case) will help to reduce shortages in the medium term.

2002 Elected service manager representative for England on the COR Radiotherapy Advisory Group Project Board for development of the Curriculum framework document. Representing the UK Radiotherapy Managers Group (a group I initiated in 2001 as no national forum existed).

Appendix V. PUBLISHED TEXTBOOK REVIEW

Journal of Radiotherapy in Practice (Journal permission for reproduction attached)

Publication for June 2009 www.journals.cambridge.org/JRP 0, 1_2 © 2009 Cambridge University Press doi:10.1017/S1460396908006602

Book Review

Radiotherapy: principles to practice. A manual for quality in treatment delivery. Second edition

Author Sue Griffiths

Medipex Ltd; ISBN 978-0-9553256-1-8; 323 pages; Hardback; £49.99

Although you should never judge a book by its cover, the new second edition of 'Radiotherapy principles to practice' by Sue Griffiths is a welcome sight. It is shiny, square-edged and pristine, lacking the characteristic well-thumbed appearance of its predecessor with its folded down corners, highlighter marks, coffee stains and other assorted evidence of abuse. But the tatty appearance of most first edition issues demonstrates the book's original appeal. It has long been valued as one of the few hallowed 'standard' texts in radiotherapy with its clear explanations and wide-ranging discussion of quality issues in practice. So has the second edition anything else to offer? When reading the new edition, it is immediately apparent that the author's distinctive clear writing style, useful diagrams, structure and patient-focus have thankfully been retained. The contents though, mirroring the radiotherapy world, have undergone drastic upheaval, expansion and restructuring to reflect changes in technology and practice. Most highly evident, perhaps, is the increased emphasis on imaging, which thanks to some restructuring and additional material can now boast an entire section instead of a mere chapter. Clearly responding to NRAG recommendations, this somewhat expanded section includes details of IGRT practice, including cone-beam and Tomotherapy equipment.

Another relevant expanded area is that of hadron therapy, which again receives more attention with a chapter on physical aspects and another on practical issues with interesting examples from clinical facilities around the world. This topic could perhaps have benefited from some more quality implications and more details on use of protons and light ions. But given the novelty, complexity and relative scarcity of the equipment this is understandable.

The techniques and equipment discussed and evaluated range from the traditional to cutting edge and it is good to see that both are used to illustrate key quality issues. It is interesting to note that the original edition denoted

conformal therapy as a 'sophisticated technique'. The inclusion of 4D and adaptive radiotherapy demonstrates how rapidly technology and practices are progressing. The patient immobilisation devices are appraised in detail and have been updated to include new materials and techniques. In particular, there is clear consideration of both patient and target tissue positioning and corresponding evaluation of methods to stabilise both. Immobilisation and treatment techniques from a range of clinical centres are combined with recommendations from literature to illustrate points throughout. The breast section, for example, features different beam matching systems and different patient positioning protocols, making the book valuable to any department. The range of techniques covered is impressive and the technique-specific quality issues are fully explained and appraised. The final section on management issues also reflects the change in the profession with the four-tier structure, returners and expert practice all featuring while maintaining the emphasis on safety that is so relevant to today's environment.

To highlight all the updates and changes would warrant an edition of JRP in itself, but the second edition clearly presents a modern and relevant approach to quality. The text features useful diagrams and photos with a selection of colour images depicting isodoses and PET scans clearly. The accompanying CD adds further value with video clips and animations of novel treatment approaches and 4D target motion. The large range of useful references are now all collated into a large section at the end rather than after each chapter, making the work more concise and the sources easier to access. The literature used features a range from essential landmark articles to the most recent research. Such a large scope covering quality and practical issues from across the full range of modern radiotherapy practice is a momentous undertaking. This either demands production of a family sized textbook that can double as a step stool or the ability to summarise issues with clarity and focus. This book benefits from the latter approach, being large enough to be useful but with minimal risk of spinal injury from use.

Where explanations are necessarily brief, the author makes good use of referencing to direct the reader to key essential further reading.

In summary, the revised second edition should maintain its status as a well-respected and valuable text. The updates and restructuring align it strongly with

trends in current practice and it is to be recommended as essential reading for anyone striving to improve quality of treatment delivery.

Pete Bridge, Senior Lecturer,
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CAMBRIDGE
UNIVERSITY PRESS

Sue Griffiths

Letter sent as PDF via email:
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Dear Ms Griffiths

"Radiotherapy: principles to practice A manual for quality in treatment delivery. Second edition Sue Griffiths Medipex Ltd; ISBN 978-0-9553256-1-8; 323 pages; Hardback; £49.99", Book review by Pete Bridge, Journal of Radiotherapy in Practice, Volume 8(2), pp 111-112, (2009).

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Publishing Assistant
email ctaylor@cambridge.org

Appendix VI

CONTRIBUTION TO COLLABORATIVE PUBLICATIONS SUBMITTED

Chronological order to show progressive radiographer involvement

Ref No Year	Candidate contribution	Contribution by others by profession
1 1985	65%	35% Dr Pearcey - contributed to study design, measurement and analysis.
2 1985	35%	65% Dr Pearcey - contributed medical knowledge and analysis, also principal author.
3 1986	65%	35% Dr Pearcey - contributed to study design, measurements and analysis.
4 1986	35%	65% Dr Pearcey - contributed medical knowledge and to study design, measurements and analysis, principal author.
9 1986	100%	Education article for radiographers
5 1987	60%	25% Dr Pearcey contributed to measurement and analysis. 15% J Thorogood (medical statistician) input statistical methods and advised on the use of statistics in the
10 1989	100%	Education article for radiographers
11 1990	100%	Education article for radiographers
6 1991	60%	20% Dr Khoury - input to analysis and manuscript. 20% A.Eddy (radiographer) - input to data collection protocol, recruited patients and co-ordinated imaging, advised on the
18 1995	35%	65% H Probst (radiographer) - patient recruitment, co-ordinating imaging, measurements and analysis and work on the manuscript as project lead.
19 1996	50%	50% C Short (radiographer) - contributing knowledge and input to the writing (joint authorship, Guest Review of radiotherapy developments)
12 1997	100%	Section in IPEM guidelines
14 1999	85%	Guideline section and Appendix 15% input from other members of the RCR COIN working group to the section
15 1999	5%	START trial management group production
20 1999	100%	Guest Editorial on radiographer staffing
13 2001	25%	Brachytherapy Chapter. Input on equipment and radiation protection by A Flynn(physicist). Editing Prof Joslin
21 2003	75%	25% Dr Delaney, Dr B Jaludin - input statistical method and tables of results, advice on manuscript
17 2004	20%	MRC RT01 trial quality assurance group production, now including S Stanley (radiographer)

16 2004	5%	MRC RT01 trial management group production
7 2005	55%	25% S Stanley (radiographer) input to questionnaire, analysis and manuscript. 20% M. Sydes, MRC statistician provided trial data and some analyses. RT01 Radiographers Group generated the raw data, on behalf of
22 2006	35%	Dr Probst (radiographer). Drafted PhD work into the manuscript as principal author.
23 2008	80%	10%A. Craig (radiographer) contributed staffing diagram. 10% M Abraham (radiographer) contributed departmental structure diagram
8 2008	25%	S Stanley (radiographer) principal author drafted manuscript and led some analyses, M Sydes MRC statistician provided trial data and some analyses RT01 Radiographers Group generated the raw data on behalf of
24 2008	100%	Textbook revision, incorporating and revising some information input by Chris Short (radiographer) to the first

Sole author of:

- a textbook
- a physicist led equipment guideline section
- 4 papers, including a Guest Editorial

Principal author on 8 publications

- 7 papers including an MRC trial paper
- a National radiotherapy guideline Section and Appendix.

Joint authorship of 1 invited Review article

Co-author with significant input on 6 publications including

- one MRC trial paper
- a chapter in a physicist/oncologist led textbook

Contributor to 3 clinical trial group papers, including significant input to one