

Research in Healthcare: why it matters

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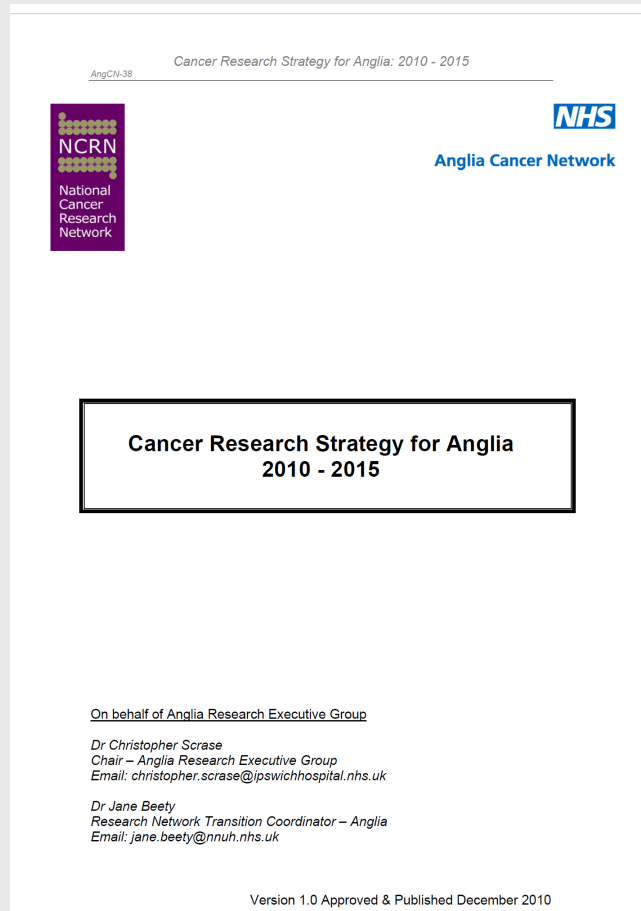
Agenda

- Personal profile
- Why research matters in health care
- What about ‘innovation’ and ‘quality improvement’
- Case example
- What has motivated me to do research (and how we made it all happen)
- How to motivate others (using QI methodology)
- What were the barriers and opportunities identified in 2012/2013 in the East of England
- What were the opportunities and barriers identified in 2024/25 in NHS Wales
- What are we wanting to put in place in Wales: Tackling Cancer Initiative
- Motivating and enabling both new and established researchers

Personal profile

- NHS consultant in Clinical Oncology in Suffolk 1998-2023
- Sub-specialty expertise in head & neck, thyroid, urological and non-melanomatous skin cancers
- Past clinical and divisional director/clinical chair
- Past secondary care doctor neighbouring CCG
- Past medical director of East of England Cancer Alliance
- Past clinical member of NHSE Radiotherapy CRG and ongoing support to quality metrics work-stream
- Past Clinical Lead for Cancer Suffolk and NE Essex Integrated Care System
- Past Faculty Board elected member and ongoing member of CESR committee & COQIAC
- Since 2023 Consultant Clinical Oncologist at NWCTC within BCUHB
- From a research perspective, 'A NHS leader who has engaged in research at multiple levels'

Research Ambition in the East of England (2010)



“As standard practice cancer patients in the Anglia Region should, wherever feasible, be offered participation in clinical studies, provided a suitable study exists, eligibility criteria can be met and the patient wishes to take part.”

Why should research matter to the Welsh population and to the NHS? HCRW July 2023

Research provides the opportunity for patients and service users to access new treatments and services, that will improve their health and well-being and contribute to reducing health inequalities in the general population.

NHS organisations that are actively involved in research see improved health outcomes and lower mortality rates, not just for those patients participating in research, but for everyone.

Research creates evidence-based services, provides evidence for NHS standards and helps organisations to find new and better ways of delivering health and social care, including better health economic outcomes.

Research provides opportunities for staff development and enhanced job roles which helps with recruitment and retention, as well as developing leaders and critical thinkers.

Research leads to economic benefits by attracting non-commercial funding and commercial income that can build the research capacity of frontline and other support services, as well as providing access to novel treatments and technologies received for free.

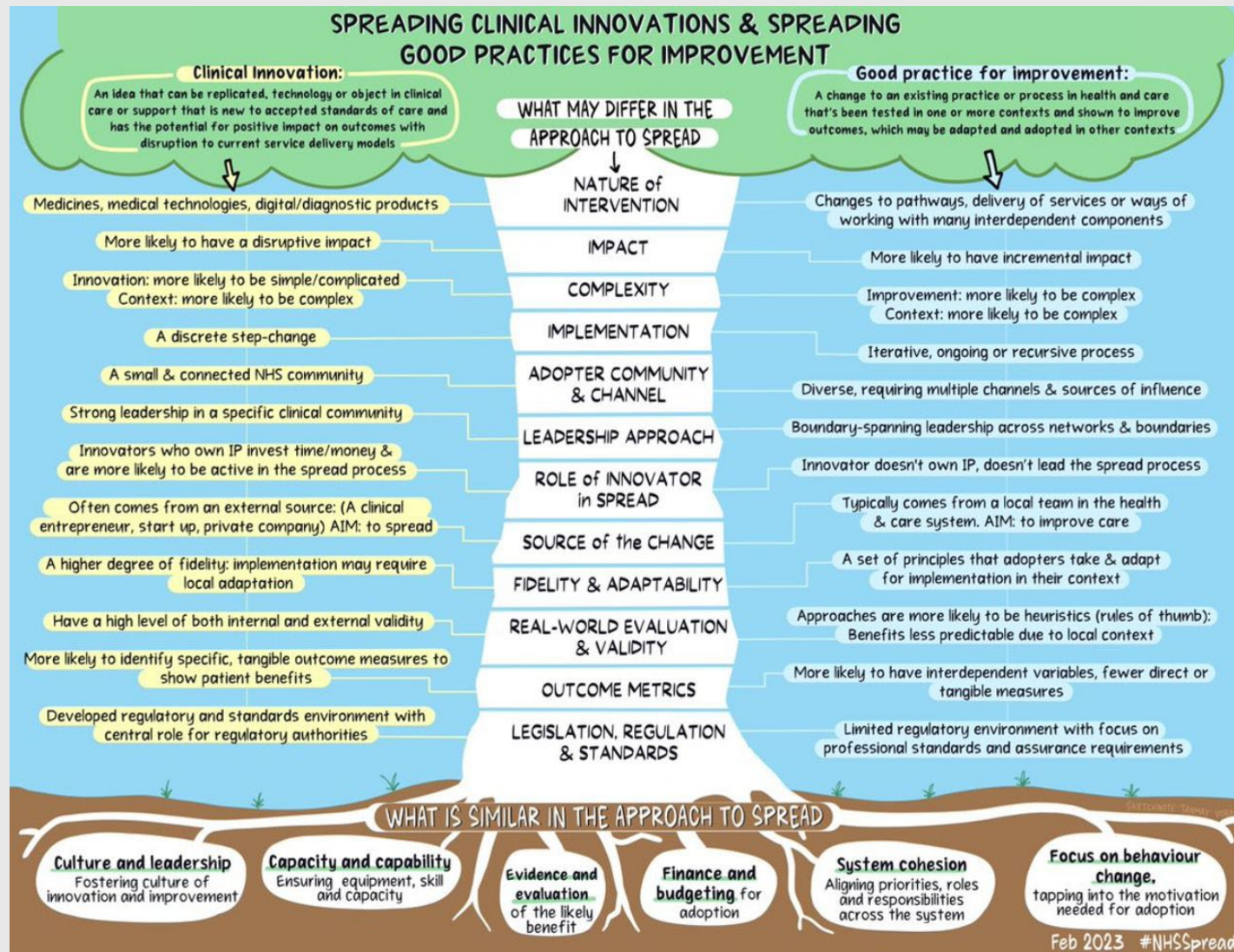
Research is an essential pillar of securing and maintaining University (Health Board) status and a key enabler for NHS Wales to deliver '*A Healthier Wales.*'

A research supportive organisation: what 'good' looks like



- Strategy: clear vision for research co-produced with the public and key stakeholders to ensure they are patient/public centred
- Clear board commitment supporting research at all levels
- Strong interdisciplinary working and cross-sector partnerships
- Secure adequate funding from HCRW to establish a sustainable R&D function and have a commitment to generate research income for non-commercial studies and commercial studies and help existing and prospective researchers secure grants
- Deliver NHS workforce plans where research is a key component
- Evidenced commitment to proactive public involvement and participation in the development and delivery of research studies; Ensuring that all research supported by NHS organisations is people-centred, supporting research to make it easier for patients, service users and members of the public to access research of relevance to them
- Communications and engagement plans demonstrate the value and importance of research; Develop plans to raise awareness of the importance of research amongst local diverse groups, ensuring proactive engagement with under-represented groups
- Develop plans to ensure research is supported during service redesign and informs the new models of service delivery

What about innovation and quality improvement?



Case example:radiotherapy

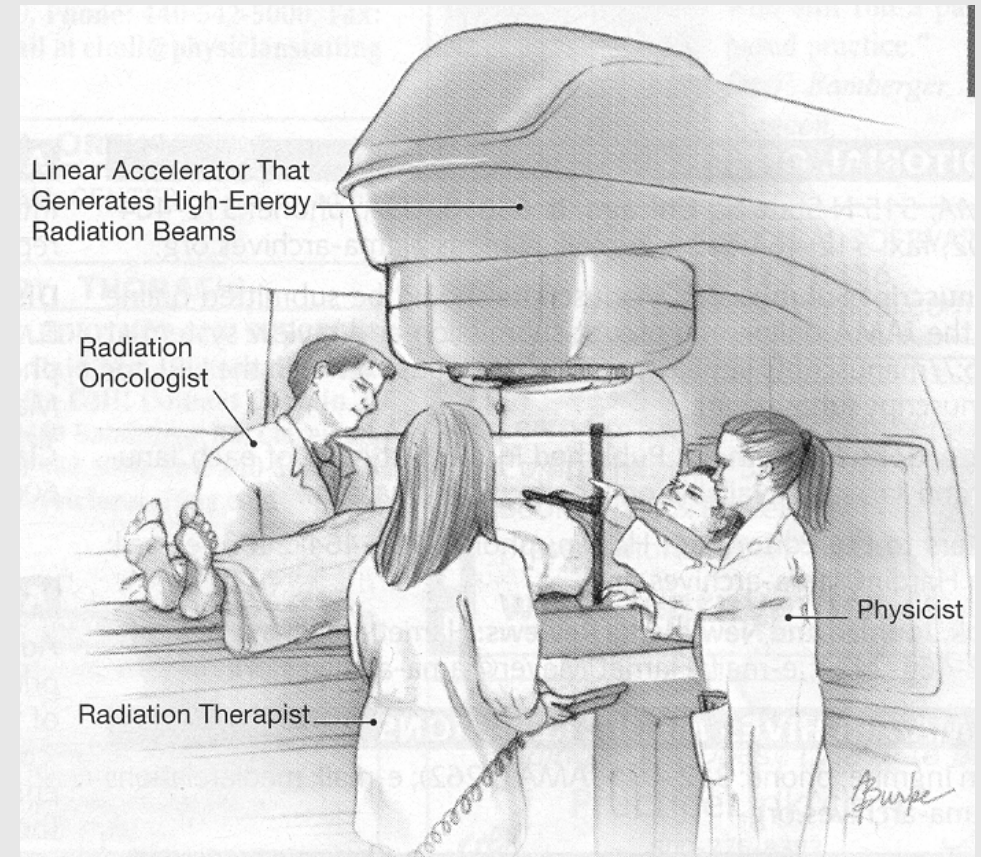
Radiotherapy: discovery of xrays to early workers to modern day team-based care



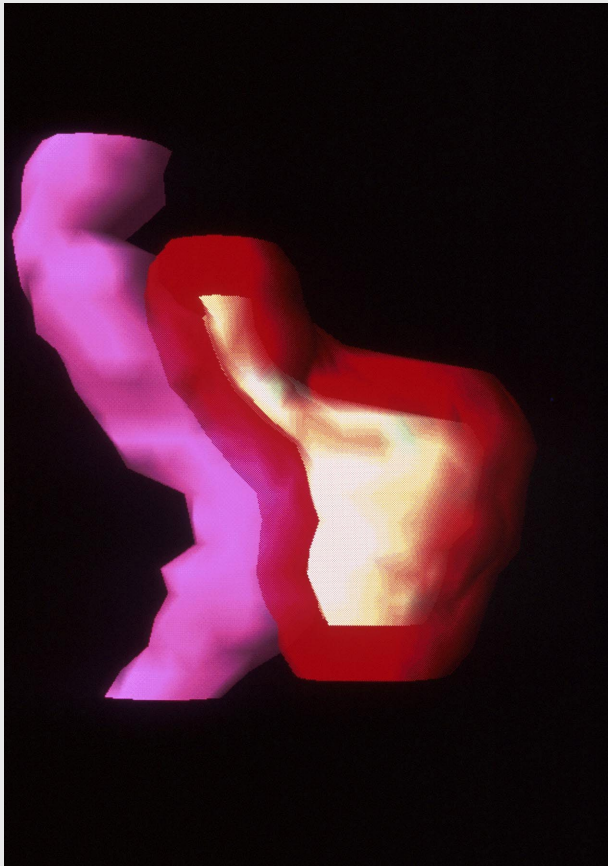
1895



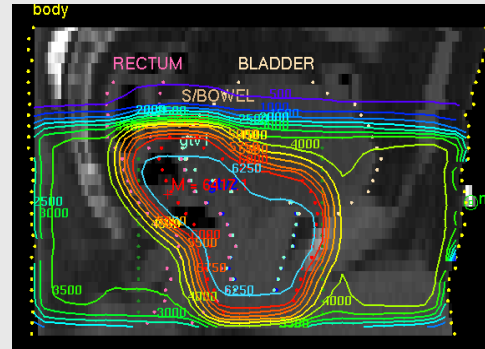
1908



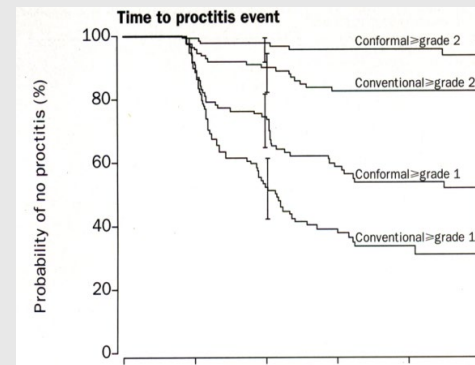
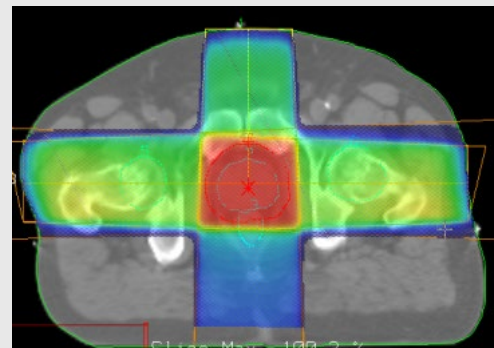
Case example: prostate cancer radiotherapy (1)



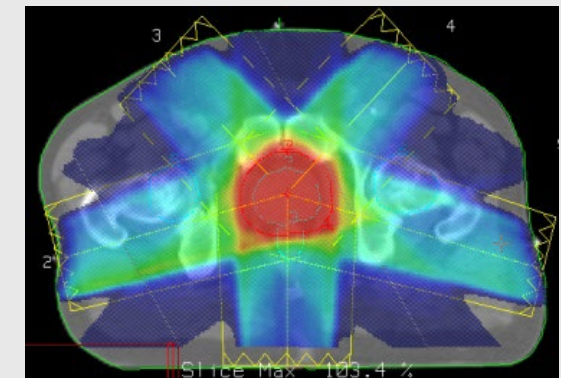
Prostate gland and proximity to the rectum



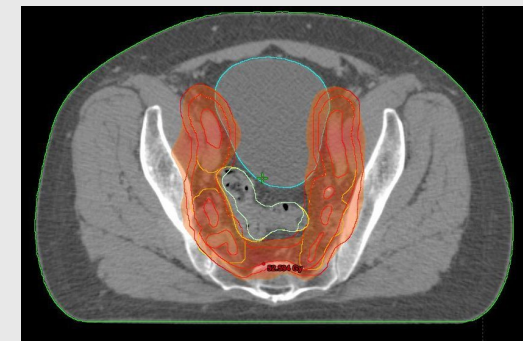
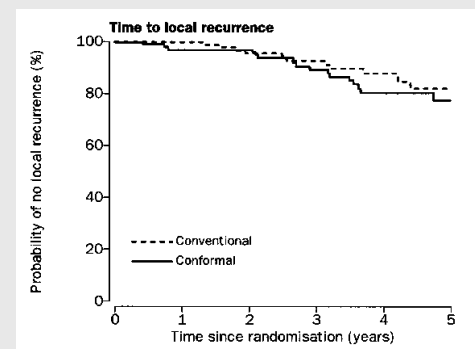
3DCRT in Sagittal and axial planes



Safety of 3DCRT (Dearnaley 1999)



Scope of IMRT in localised and locally advanced Pca treating the pelvic nodes



Case example: prostate cancer radiotherapy (2)

Escalated-dose versus standard-dose conformal radiotherapy in prostate cancer: first results from the MRC RT01 randomised controlled trial

David P Dearnaley, Matthew R Sydes, John D Graham, Edwin G Aird, David Bottomley, Richard A Cowan, Robert A Huddart, Chakrith C Jose, John HJ Matthews, Jeremy Millar, A Rallo Moore, Rachel C Morgan, J Martin Russell, Christopher D Scrase, Richard J Stephens, Isabel Syndikus, Mahesh KB Parmar, on behalf of the RT01 collaborators

Summary
Background In men with localised prostate cancer, conformal radiotherapy (CFRT) could deliver higher doses of radiation than does standard-dose conventional radical external-beam radiotherapy, and could improve long-term efficacy, potentially at the cost of increased toxicity. We aimed to present the first analyses of effectiveness from the MRC RT01 randomised controlled trial.

Methods The MRC RT01 trial included 843 men with localised prostate cancer who were randomly assigned to standard-dose CFRT or escalated-dose CFRT, both administered with neoadjuvant androgen suppression. Primary endpoints were biochemical-progression-free survival (bPFS), freedom from local progression, metastases-free survival, overall survival, and late toxicity scores. The toxicity scores were measured with questionnaires for physicians and patients that included the Radiation Therapy Oncology Group (RTOG), the Late Effects on Normal Tissue: Subjective/Objective/Management (LENT/SOM) scales, and the University of California, Los Angeles Prostate Cancer Index (UCLA PCI) scales. Analysis was done by intention to treat. This trial is registered at the Current Controlled Trials website <http://www.controlled-trials.com/ISRCTN47772397>.

Findings Between January, 1998, and December, 2002, 843 men were randomly assigned to escalated-dose CFRT (n=422) or standard-dose CFRT (n=421). In the escalated group, the hazard ratio (HR) for bPFS was 0.67 (95% CI 0.53–0.85, p=0.0007). We noted 71% bPFS (108 cumulative events) and 60% bPFS (149 cumulative events) by 5 years in the escalated and standard groups, respectively. HR for clinical progression-free survival was 0.69 (0.47–1.02; p=0.064); local control was 0.65 (0.36–1.18; p=0.16); freedom from salvage androgen suppression was 0.78 (0.57–1.07; p=0.12); and metastases-free survival was 0.74 (0.47–1.18; p=0.21). HR for late bowel toxicity in the escalated group was 1.47 (1.12–1.92) according to the RTOG (grade ≥2) scale; 1.44 (1.16–1.80) according to the LENT/SOM (grade ≥2) scales; and 1.28 (1.03–1.60) according to the UCLA PCI (score ≥30) scale. 33% of the escalated and 24% of the standard group reported late bowel toxicity within 5 years of starting treatment. HR for late bladder toxicity according to the RTOG (grade ≥2) scale was 1.36 (0.90–2.06), but this finding was not supported by the LENT/SOM (grade ≥2) scales (HR 1.07 [0.90–1.29]), nor the UCLA PCI (score ≥30) scale (HR 1.05 [0.81–1.36]).

Interpretation Escalated-dose CFRT with neoadjuvant androgen suppression seems clinically worthwhile in terms of bPFS, progression-free survival, and decreased use of salvage androgen suppression. This additional efficacy is offset by an increased incidence of longer term adverse events.

Introduction
Prostate cancer is now the most commonly diagnosed cancer in men in the UK, USA, and western Europe; in 2000, the global estimate of deaths per year was 263 000.¹ The introduction of PSA testing has led to an increasing proportion of patients presenting with localised disease. Management options are controversial and include radical prostatectomy, external-beam radiotherapy, brachytherapy, and active surveillance or monitoring of men with favourable prognostic factors² or, alternatively, watchful waiting for those who are unsuitable for a radical curative treatment approach. External-beam radiotherapy might be most appropriate for men with intermediate-risk or high-risk features,^{3,4} and is associated with long-term disease control in most men with prostate cancer.⁵ Advances in radiation technology have enabled more precise and accurate treatment that allows the delivery of higher radiation doses and improved disease control while maintaining an acceptable frequency of side-effects. Conventional radical external-beam radiotherapy is limited to doses of 64–70 Gy in 1.8–2.0 Gy fractions because of the risk of long-term toxic effects to the bladder and rectum. Within 5 years of being treated with this type of radiotherapy, up to 33% of patients will have relapsed (either clinically or biochemically, ie, increasing prostate serum antigen [PSA] concentrations) or died.⁶ Conformal radiotherapy (CFRT) techniques use linear accelerators with multileaf collimators or customised shaped blocks to shape the radiotherapy beam. Due to

<http://oncology.thelancet.com> Vol 8 June 2007

- Published in 2007
- Demonstrated that 74Gy/37# > 64Gy/32# in terms of progression free survival
- Enabled 3DCRT to be ‘rolled out’ through a clinical trial

Case example: prostate cancer radiotherapy (3)

Escalated-dose versus control-dose conformal radiotherapy for prostate cancer: long-term results from the MRC RT01 randomised controlled trial

David P Dearnaley, Gordana Jovic, Isabel Syndikus, Vincent Khoo, Richard A Cowan, John D Graham, Edwin G Aird, David Bottomley, Robert A Huddart, Chakrath C Jose, John H L Matthews, Jeremy L Millar, Claire Murphy, J Martin Russell, Christopher D Scrase, Mahesh K B Parmar, Matthew R Sydes

Summary

Background The aim of this trial was to compare dose-escalated conformal radiotherapy with control-dose conformal radiotherapy in patients with localised prostate cancer. Preliminary findings reported after 5 years of follow-up showed that escalated-dose conformal radiotherapy improved biochemical progression-free survival. Based on the sample size calculation, we planned to analyse overall survival when 190 deaths occurred; this target has now been reached, after a median 10 years of follow-up.

Methods RT01 was a phase 3, open-label, international, randomised controlled trial enrolling men with histologically confirmed T1b–T3a, N0, M0 prostate cancer with prostate specific antigen of less than 50 ng/mL. Patients were randomly assigned centrally in a 1:1 ratio, using a computer-based minimisation algorithm stratifying by risk of seminal vesicle invasion and centre to either the control group (64 Gy in 32 fractions, the standard dose at the time the trial was designed) or the escalated-dose group (74 Gy in 37 fractions). Neither patients nor investigators were masked to assignment. All patients received neoadjuvant androgen deprivation therapy for 3–6 months before the start of conformal radiotherapy, which continued until the end of conformal radiotherapy. The coprimary outcome measures were biochemical progression-free survival and overall survival. All analyses were done on an intention-to-treat basis. Treatment-related side-effects have been reported previously. This trial is registered, number ISRCTN4772397.

Findings Between Jan 7, 1998, and Dec 20, 2001, 862 men were registered and 843 subsequently randomly assigned: 422 to the escalated-dose group and 421 to the control group. As of Aug 2, 2011, 236 deaths had occurred: 118 in each group. Median follow-up was 10·0 years (IQR 9·1–10·8). Overall survival at 10 years was 71% (95% CI 66–75) in each group (hazard ratio [HR] 0·99, 95% CI 0·77–1·28; $p=0·96$). Biochemical progression or progressive disease occurred in 391 patients (221 [57%] in the control group and 170 [43%] in the escalated-dose group). At 10 years, biochemical progression-free survival was 43% (95% CI 38–48) in the control group and 55% (50–61) in the escalated-dose group (HR 0·69, 95% CI 0·56–0·84; $p=0·0003$).

Interpretation At a median follow-up of 10 years, escalated-dose conformal radiotherapy with neoadjuvant androgen deprivation therapy showed an advantage in biochemical progression-free survival, but this advantage did not translate into an improvement in overall survival. These efficacy data for escalated-dose treatment must be weighed against the increase in acute and late toxicities associated with the escalated dose and emphasise the importance of use of appropriate modern radiotherapy methods to reduce side-effects.

Funding UK Medical Research Council.

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Introduction

External beam radiotherapy is one of the standard curative options for men with localised prostate cancer and is particularly appropriate for men with intermediate-risk or high-risk disease.^{1,2} Improved radiotherapy techniques, such as conformal radiotherapy, allow high treatment doses to be given safely^{3,4} and several phase 3 randomised controlled trials of dose escalation have reported improved biochemical progression-free survival.^{5–10} The Medical Research Council (MRC) RT01 trial is the largest of these trials to have reported results, and since its initial report of results dose-escalated conformal radiotherapy has been

the standard of care in the UK since 2008.¹ The trial mandated the use of short-course neoadjuvant androgen deprivation therapy (ADT); neoadjuvant ADT has since been shown to improve overall and cancer-specific survival in patients with advanced localised disease.^{11,12}

The aim of the RT01 trial was to assess the effect of dose-escalation on overall survival, biochemical progression-free survival, and toxicity, by comparing doses of 74 Gy and 64 Gy delivered by use of conformal radiotherapy techniques. 64 Gy in 32 fractions was chosen as the radiotherapy schedule for the control group in our randomised trial, because that was the standard

- Published in 2014
- 10 years results reaffirmed benefits of the higher dose of 74Gy/37#
- PFS improved but no improvement in OS
- ‘Efficacy data for escalated-dose treatment must be weighed against the increase in acute and late toxicities associated with the escalated dose and emphasise the importance of use of appropriate modern radiotherapy methods to reduce side-effects’
- It was around this time that IMRT was emerging as an exciting more advanced approach in radiotherapy delivery

Case example: prostate cancer radiotherapy (4)

Conventional versus hypofractionated high-dose intensity-modulated radiotherapy for prostate cancer: 5-year outcomes of the randomised, non-inferiority, phase 3 CHHiP trial

David Deamaley, Isabel Syndikus, Helen Mossop, Vincent Khoo, Alison Birtle, David Bloomfield, John Graham, Peter Kirkbride, John Logue, Zafar Malik, Julian Money-Kyrle, Joe M O'Sullivan, Miguel Panades, Chris Parker, Helen Patterson*, Christopher Scrase, John Staffurth, Andrew Stockdale, Jean Tremlett, Margaret Bidmead, Helen Mayles, Olivia Naismith, Chris South, Annie Gao, Clare Cruickshank, Shama Hassan, Julia Pugh, Clare Griffin, Emma Hall, on behalf of the CHHiP investigators

Summary

Background Prostate cancer might have high radiation-fraction sensitivity that would give a therapeutic advantage to hypofractionated treatment. We present a pre-planned analysis of the efficacy and side-effects of a randomised trial comparing conventional and hypofractionated radiotherapy after 5 years follow-up.

Methods CHHiP is a randomised, phase 3, non-inferiority trial that recruited men with localised prostate cancer (pT1b-T3aN0M0). Patients were randomly assigned (1:1:1) to conventional (74 Gy delivered in 37 fractions over 7·4 weeks) or one of two hypofractionated schedules (60 Gy in 20 fractions over 4 weeks or 57 Gy in 19 fractions over 3·5 weeks) all delivered with intensity-modulated techniques. Most patients were given radiotherapy with 3-6 months of neoadjuvant and concurrent androgen suppression. Randomisation was by computer-generated random permuted blocks, stratified by National Comprehensive Cancer Network (NCCN) risk group and radiotherapy treatment centre, and treatment allocation was not masked. The primary endpoint was time to biochemical or clinical failure; the critical hazard ratio (HR) for non-inferiority was 1·208. Analysis was by intention to treat. Long-term follow-up continues. The CHHiP trial is registered as an International Standard Randomised Controlled Trial, number ISRCTN97182923.

Findings Between Oct 18, 2002, and June 17, 2011, 3216 men were enrolled from 71 centres and randomly assigned (74 Gy group, 1065 patients; 60 Gy group, 1074 patients; 57 Gy group, 1077 patients). Median follow-up was 62·4 months (IQR 53·9-77·0). The proportion of patients who were biochemical or clinical failure free at 5 years was 88·3% (95% CI 86·0-90·2) in the 74 Gy group, 90·6% (88·5-92·3) in the 60 Gy group, and 85·9% (83·4-88·0) in the 57 Gy group. 60 Gy was non-inferior to 74 Gy (HR 0·84 [90% CI 0·68-1·03], $p_{\text{non}}=0·0018$) but non-inferiority could not be claimed for 57 Gy compared with 74 Gy (HR 1·20 [0·99-1·46], $p_{\text{non}}=0·48$). Long-term side-effects were similar in the hypofractionated groups compared with the conventional group. There were no significant differences in either the proportion or cumulative incidence of side-effects 5 years after treatment using three clinician-reported as well as patient-reported outcome measures. The estimated cumulative 5 year incidence of Radiation Therapy Oncology Group (RTOG) grade 2 or worse bowel and bladder adverse events was 13·7% (111 events) and 9·1% (66 events) in the 74 Gy group, 11·9% (105 events) and 11·7% (88 events) in the 60 Gy group, 11·3% (95 events) and 6·6% (57 events) in the 57 Gy group, respectively. No treatment-related deaths were reported.

Interpretation Hypofractionated radiotherapy using 60 Gy in 20 fractions is non-inferior to conventional fractionation using 74 Gy in 37 fractions and is recommended as a new standard of care for external-beam radiotherapy of localised prostate cancer.

Funding Cancer Research UK, Department of Health, and the National Institute for Health Research Cancer Research Network.

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Introduction

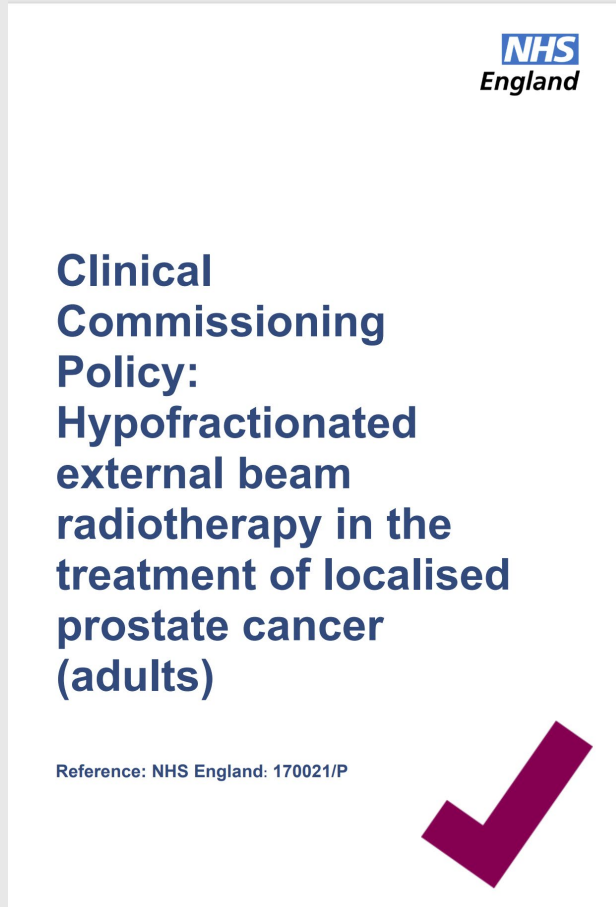
Prostate cancer is the most common cancer in men in the UK, with 41736 new cases in 2011.¹ Since the introduction of prostate-specific antigen (PSA) testing, most men diagnosed have localised disease. Management options include external-beam radiotherapy, brachytherapy, radical

prostatectomy, active surveillance (for men with low-risk disease), and watchful waiting (for those unsuitable for radical curative treatment), with management choices often affected by potential treatment-related toxic effects. Prostate cancer and its treatment are the leading cause of cancer years lived with disability.²

www.thelancet.com/oncology Vol 17 August 2016

- Published in 2016
- Demonstrated that 60Gy/20# was ‘non-inferior’ to then standard of 74Gy/37#
- Centres embraced the trial as a means of implementing IMRT

Case example: prostate cancer radiotherapy (5)



- Trial management group and wider professional community were sighted of the results early
- Many centres embraced the new standard of 60Gy/20# ahead of NICE guidance and NHSE commissioning recommendations (2017)

Case example: prostate cancer radiotherapy (6)

Combined androgen deprivation therapy and radiation therapy for locally advanced prostate cancer: a randomised, phase 3 trial

Padraig Warde*, Malcolm Mason*, Keyue Ding, Peter Kirkbride, Michael Brundage, Richard Cowan, Mary Gospodarowicz, Karen Sanders, Edmund Kostashuk, Greg Swanson, Jim Barber, Andrea Hiltz, Mahesh K B Parmar, Jinka Sathya, John Anderson, Charles Hayter, John Hetherington, Matthew R Sydes†, Wendy Parulekar†, for the NCIC CTG PR.3/MRC UK PR07 investigators

Summary

Background Whether the addition of radiation therapy (RT) improves overall survival in men with locally advanced prostate cancer managed with androgen deprivation therapy (ADT) is unclear. Our aim was to compare outcomes in such patients with locally advanced prostate cancer.

Methods Patients with: locally advanced (T3 or T4) prostate cancer (n=1057); or organ-confined disease (T2) with either a prostate-specific antigen (PSA) concentration more than 40 ng/mL (n=119) or PSA concentration more than 20 ng/mL and a Gleason score of 8 or higher (n=25), were randomly assigned (done centrally with stratification and dynamic minimisation, not masked) to receive lifelong ADT and RT (65–69 Gy to the prostate and seminal vesicles, 45 Gy to the pelvic nodes). The primary endpoint was overall survival. The results presented here are of an interim analysis planned for when two-thirds of the events for the final analysis were recorded. All efficacy analyses were done by intention to treat and were based on data from all patients. This trial is registered at controlledtrials.com as ISRCTN24991896 and Clinicaltrials.gov as NCT00002633.

Results Between 1995 and 2005, 1205 patients were randomly assigned (602 in the ADT only group and 603 in the ADT and RT group); median follow-up was 6.0 years (IQR 4.4–8.0). At the time of analysis, a total of 320 patients had died, 175 in the ADT only group and 145 in the ADT and RT group. The addition of RT to ADT improved overall survival at 7 years (74%, 95% CI 70–78 vs 66%, 60–70; hazard ratio [HR] 0.77, 95% CI 0.61–0.98, p=0.033). Both toxicity and health-related quality-of-life results showed a small effect of RT on late gastrointestinal toxicity (rectal bleeding grade >3, three patients (0.5%) in the ADT only group, two (0.3%) in the ADT and RT group; diarrhoea grade >3, four patients (0.7%) vs eight (1.3%); urinary toxicity grade >3, 14 patients (2.3%) in both groups).

Interpretation The benefits of combined modality treatment—ADT and RT—should be discussed with all patients with locally advanced prostate cancer.

Funding Canadian Cancer Society Research Institute, US National Cancer Institute, and UK Medical Research Council.

Introduction

913 000 new cases of prostate cancer and 215 000 deaths occurred worldwide in 2008.¹ In the USA prostate cancer is the most frequently diagnosed cancer in men and is second only to lung cancer as a cause of cancer deaths.²

The proportion of patients presenting with locally advanced disease (at stages T3 or T4) at diagnosis has decreased in the past 20 years, largely as a result of widespread prostate-specific antigen (PSA) screening.³ However, locally advanced disease is still a common clinical challenge and its management controversial.⁴

In a randomised trial of patients with locally advanced disease, comparing orchiectomy alone, radiation therapy (RT) alone, and combined RT and orchiectomy, no differences in survival between the three groups was recorded. However, this study had poor accrual and the number of patients randomised was not sufficient to detect clinically relevant survival differences. Data that emerged in the early 1990s suggest that adjuvant androgen deprivation therapy (ADT) improves outcomes compared

with RT alone. However, in view of the adoption of early ADT for management of patients with locally advanced disease, the benefit of RT is still uncertain. Our aim was to assess the role of local RT in addition to ADT in patients with locally advanced prostate cancer.

Methods

Participants

The NCIC Clinical Trials Group (NCIC CTG) PR.3/MRC UK PR07 trial was an unmasked, randomised trial done in collaboration with the Eastern Cooperative Oncology Group and the Southwest Oncology Group. At the study's initiation in 1995, the criteria for participation in the trial were histologically confirmed prostate adenocarcinoma with locally advanced disease (clinical tumour stage T3 or T4, N0 or NX, or M0 disease). In 1999, the entry criteria were broadened to include patients with clinical T2 tumours with either PSA concentration of more than 40 ng/mL or both T2 and PSA concentration of more than 20 ng/mL.

www.thelancet.com Vol 378 December 17/24/31, 2011

- Published in 2011
- Demonstrated that the addition of prostate (pelvic node) radiotherapy should be offered to patients with locally advanced disease
- MRC PR07 was a difficult study for me to recruit to as my equipoise was slanted to radiotherapy should be standard of care in locally advanced disease
- Mindful of my (and others) reservations over the additional toxicity I only treated the prostate and not the nodes as well
- Study alluded to toxicity and potential for mitigating against toxicity with more advanced radiotherapy techniques

(IMRT)

Case example: prostate cancer radiotherapy (7)



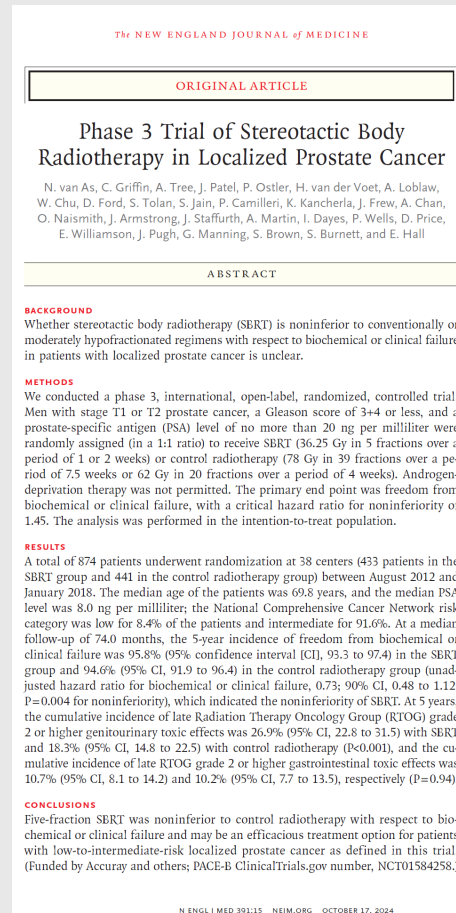
- Published in 2019
- Designed to establish the toxicity profile of high-dose pelvic lymph node IMRT and to assess whether it is safely deliverable at multiple centres
- PIVOTAL demonstrated that high-dose pelvic lymph node IMRT can be delivered at multiple centres with a modest side effect profile.
- Although safety data from the study were encouraging, the impact of prostate & pelvic node IMRT on disease control remained (then) to be established.

Case example: prostate cancer radiotherapy (8)



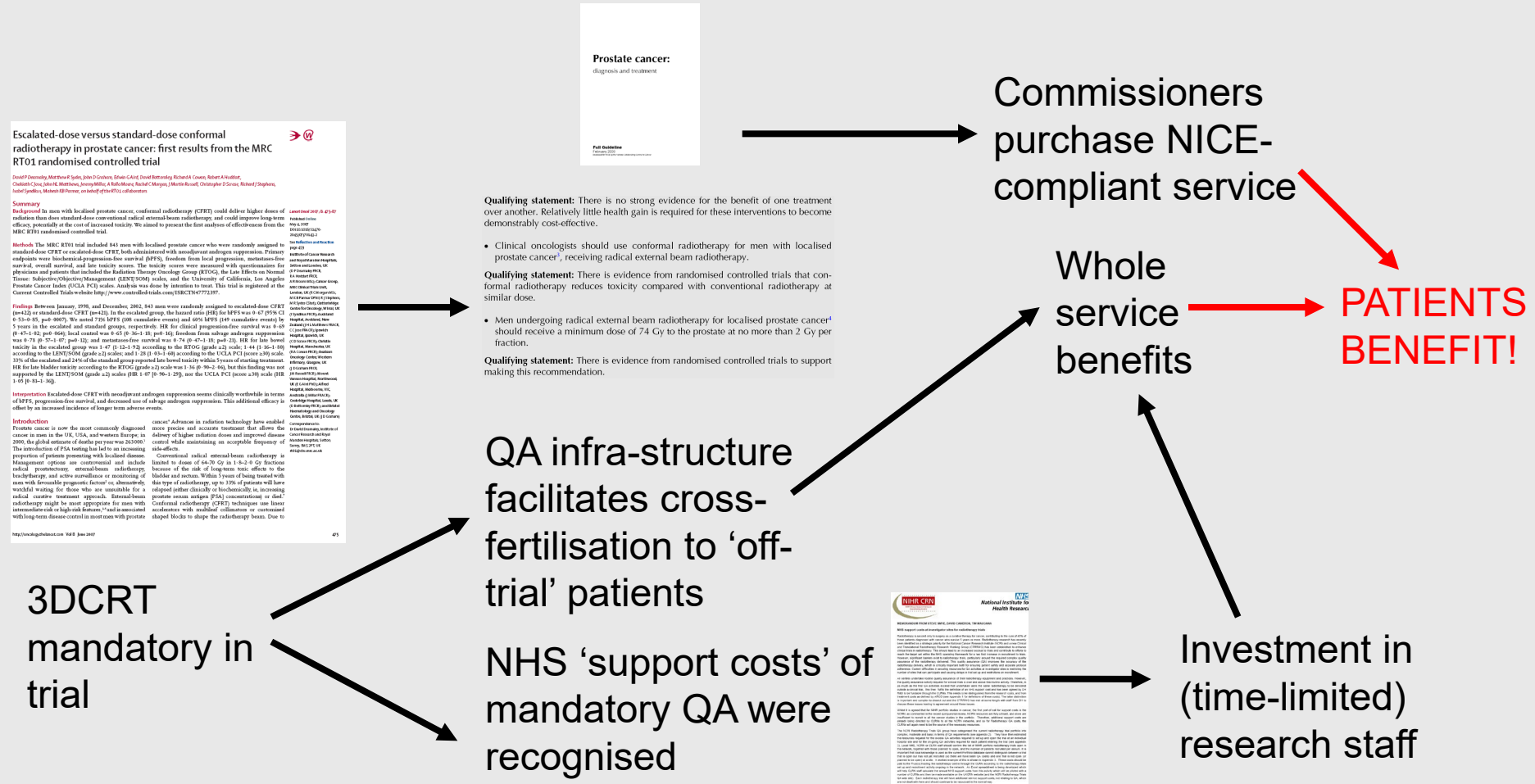
- Published in 2020
- Demonstrated that it is possible to deliver a complex radiotherapy trial supported by a comprehensive RTQA programme across a large number of UK centres, due to the ongoing enthusiasm and engagement of the UK radiotherapy community.
- The primary endpoint in PIVOTALboost is failure free survival which will take 5–10 years to complete
- With continued pressures on the NHS extended follow up puts a burden on the clinical and research teams. Many prostate cancer patients are discharged from secondary care after 3–5 years so the trial team will explore options for efficient collection of accurate follow-up data.
- PIVOTALboost is an ambitious and potentially practice changing trial, with an efficient design addressing a number of relevant questions using modern radiotherapy techniques.

Case example: prostate cancer radiotherapy (9)



- Published in 2024
- Demonstrated that 5 fraction SBRT (SABR) was non-inferior to 78Gy/39# and 62Gy/20# in terms of biochemical and clinical failure
- 36.25Gy/5# now recommended for low to intermediate risk group patients
- Adopted by NHSW (2024) and NHSE (2025)

Impact thus of a successful Clinical Trial such as RT01



What has motivated me to do research

- Impact of my mentors
- ‘Professional community’ that enhances care
- ‘Recognition’ (especially as one in a smaller centre)
- Enabled me to ensure my practice is up-to-date and evidenced (RTTQA bench-marking cases):

RTTQA PIVOTALboost
Radiotherapy Trials Quality Assurance

Report on PIVOTALboost
Prospective Outlining Case Review - PB24067 Ipswich

Trial Number:	PB24067
Trial Arm:	D2: Prostate and pelvic IMRT and prostate boost
Submission Date:	09/02/2022
Outlined by:	Christopher Scrase
Reviewed by:	Dr Isabel Syddikus
Review Date:	09/02/2022

1 Introduction
Results have been reported using a traffic light scheme, classifying the submitted outlines as:

Acceptable As per protocol, no changes needed

Acceptable variation The variation is within acceptable limits and does not require resubmission. However, please note the comments made

Unacceptable variation The variation is outside acceptable limits. Please re-submit that outline unless otherwise stated in the report.

Target volume	Variation from trial protocol	Comments
CTVp	Acceptable	Superior prostate margin could be reduced by one slice to confidently exclude bladder mucosa. The location of the apex was correct. We agreed that the location of the tumour bearing area justified a small extra-prostatic margin in that zone only.
CTVp+ov	Acceptable	
Overall mark	Acceptable	

2.3.2 Prostate Boost (arms C2/D2 only)

GTVP	Variation from trial protocol	Comments
Subtable boost volume <50% CTVp and >5mm size	Acceptable	
Encompassed by CTVp	Acceptable	
Overall mark	Acceptable	

After review and local discussion with radiologist, there is no tumour volume in the left lobe. The disease extends into the fibromuscular stroma but not beyond. You edited GTVP according to our discussion.

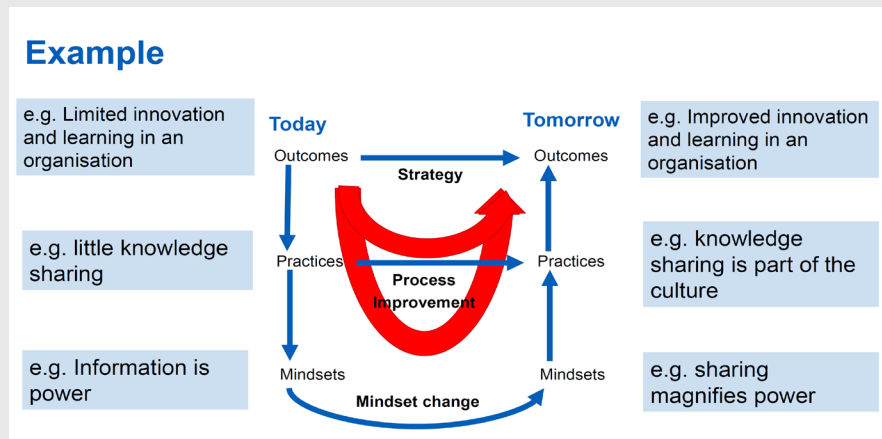
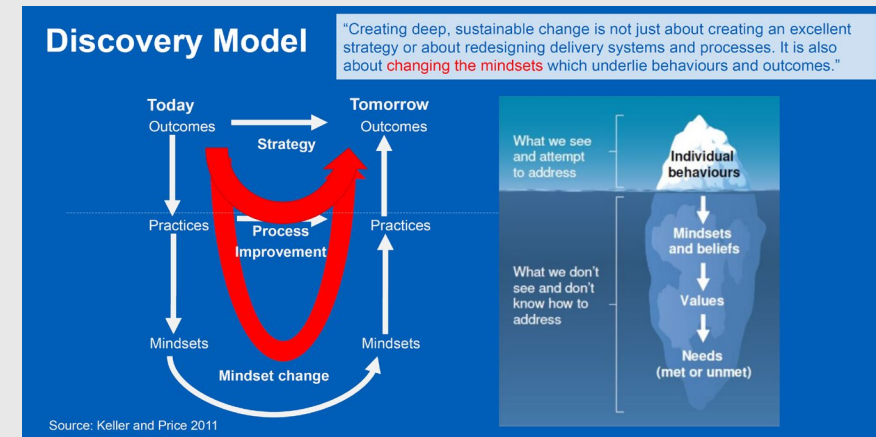
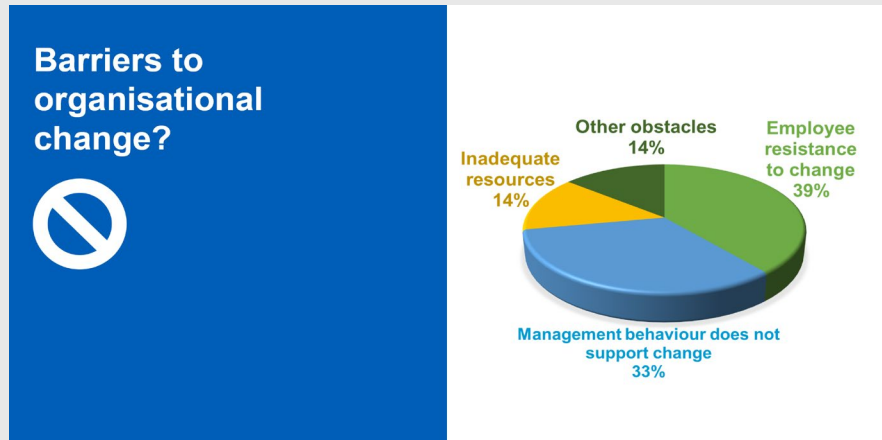
2.3.3 Pelvic Nodes (arms B/D only)

Target volume	Variation from trial protocol	Comments
Vessel	Acceptable	
CTVn	Acceptable	
Bladder outline excluded from CTVn	Acceptable	
Bowel outline excluded from CTVn	Acceptable	

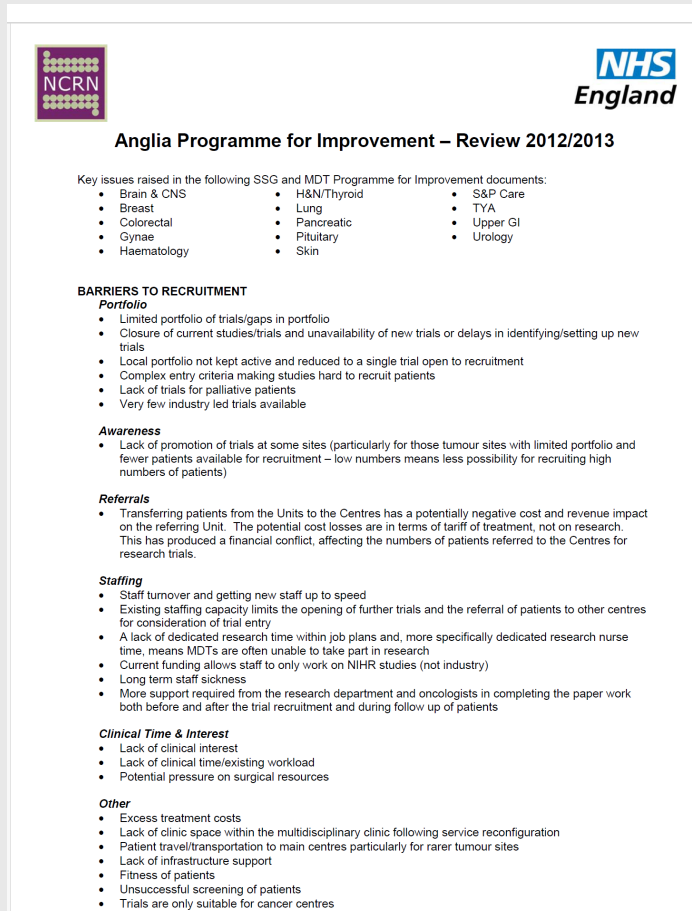
‘How’ we made it happen?

- Engaged and impactful R&D team
- Culture of ‘can do’ amongst the service team and support services
- Integrating research team into the MDT meetings
- Underpinned by regional work of embedding MDT and SSG (NCG or CSG) research leads

How to motivate others: consider embedding research as a quality improvement initiative



What were the opportunities and barriers in 2012/2013 (in East of England)



Opportunities (not exhaustive)

Portfolio

- Continue to review international and national trials for suitable trials to open locally
- Continue to encourage more interest and research from the surgical teams
- Engage our surgical/nursing/AHP colleagues in trial design and/or as key co-workers to oncology-led trials

Networking and highlighting Anglia portfolio

- Continue to provide research reports to ensure continued communication on trials open and recruiting, including network comparisons, to facilitate engagement and interest
- Ensure our reputation amongst central clinical trials units and pharmaceutical companies for high quality and timely reporting of data, events and outcomes continues
- SSG to work with and provide help/support for those hospitals with low recruitment to help improve any obstacles

What were the opportunities and barriers identified in 2024/25 (in NHS Wales)



• Inconsistent Designation of Research Leads

The lack of designated cancer research leads in some organisations leads to variability in research focus and coordination. Designated leads are essential for driving research initiatives, securing funding, and fostering collaboration among researchers.

Limited Inclusion in Appraisals and Meetings

The inconsistent inclusion of clinical research in appraisals and meetings affects its prioritisation within organisations. Recognising and discussing research activities during appraisals and meetings can motivate staff and ensure that research remains a key focus.

Organisational Boundaries and Resource Constraints

Organisational boundaries and resource constraints are significant barriers to trial recruitment and participation. These barriers include service capacity issues, financial impediments, and lack of dedicated time, staff, and infrastructure.

Communication Gaps

There are gaps in how information about clinical trials is disseminated within and across organisations. Effective communication channels are essential for ensuring that researchers are aware of ongoing and upcoming trials.

What are we wanting to put in place in Wales?



Ymchwil Iechyd
a Gofal **Cymru**
Health and Care
Research **Wales**



Canolfan
Ymchwil
Cancer
Cymru | **Wales**
Cancer
Research
Centre



GIG
CYMRU
NHS
WALES

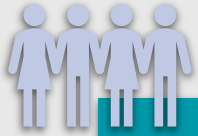
Rhwydwaith
Canser Cymru
Wales Cancer
Network

Tackling cancer through research
Collaborating and delivering for patients in Wales

Tackling cancer through research initiative

- Deliver better cancer outcomes and survival for Welsh patients
- Reduce healthcare inequalities
- Attract greater commercial cancer clinical trial activity into Wales
- Increase patient access to new and novel treatments via these trials
- Attract investment in Welsh healthcare, employment and wider economy

The ambition



- **Increase cancer patient recruitment** to commercial clinical studies by four-fold (400%) to over 1000 patients, by Q4 2027.



- **Increase access** to commercial clinical studies to patients with a diverse range of cancers, and from a diverse range of backgrounds and geographies



- **Increase the proportion of Phase 3 trials** in Wales's commercial cancer trial portfolio to >50% by 2027

Working with industry: the ‘why (not)?’

- Cancer patients miss out on opportunities to access new and novel cancer treatments or have to travel to England to access them. Both scenarios *may* result in outcomes being compromised as a result
- The NHS in Wales has to fund alternative, often sub-optimal, treatments and misses out on drug and standard of care cost savings that trial treatment would provide. It is estimated that industry funding of clinical trials helps generate £1.2 billion of NHS savings in the UK and supports 13,000 NHS jobs
- NHS service and staff miss out on learnings gained during a clinical trial that streamline subsequent implementation of the findings into routine clinical care
- The Welsh economy misses out on income from commercial trial activity. Industry clinical trials contributed £7.4 billion of gross value added (GVA) to the UK economy and supported a total of 65,000 jobs

Action plan



Workstreams (National Clinical Lead Prof Richard Adams)

1. Coordinated Research Delivery (Jayne Goodwin)
2. NHS performance frameworks and cancer metrics (Vi Sarma/Claire Bond)
3. **Embedding in Welsh clinical service system (Tom Crosby/Christopher Scrase)**
4. Embedding in NHS job descriptions (Helen Grindell)
5. Investing in infrastructure via VPAG (Nicola Williams)
6. Diagnostic/genomic infrastructure (Sian Morgan)
7. Development of PIs (Nicola Williams)
8. Communications and Engagement (Felicity Waters) - incorporates patient, public, clinician and industry plan

Embedding research into the Welsh Clinical Service System

‘How’

- Explorative discussions with respondents to ‘MDT’ survey
- Health Board and cross-cutting representation meeting planned for late July
- Anticipate both pan-Wales and health-board issues and solutions

MDT and CSG research leads

The main role of a Cancer Research Lead is in encouraging clinicians and the wider multidisciplinary Team (MDT) to be research-active and in doing so to serve as a catalyst for integrating research into everyday clinical practice.

- Working in partnership with the network R&I clinical lead they **identify site-specific barriers and priorities** for research to inform discussions with stakeholders.
- Advocating for Research Engagement: The Research Lead actively promotes **the value of research** among clinicians and the wider MDT.
- **Facilitating Access** to Research Opportunities: supported by the Network R&I clinical lead and R&I team they identify and communicate relevant research opportunities.
- Fostering a **Research Culture within the CSG as a whole**: By creating an environment that values and rewards research activity, the Research Lead encourages a culture where clinicians and MDTs see research as an integral part of their roles. This can include recognising research achievements, integrating research discussions into regular team meetings, and celebrating successes within the team.
- The Research Lead collaborates closely with clinicians, multidisciplinary teams (MDTs), and key stakeholders, including patients and industry partners, to ensure that research activities are not only aligned with the immediate clinical needs and priorities but also **explore innovative, long-term solutions**. By balancing clinical relevance with forward-thinking research, this role helps bridge the gap between early-stage research and direct patient benefit. Facilitate sharing of best practices and collective learning through periodic meetings (supported by Cancer Network).

Enabling/motivating established researchers



Canolfan
Ymchwil
Cancer
Cymru

Wales
Cancer
Research
Centre

Call for expressions of interest: Research time for clinicians for cancer clinical trial activity

The Wales Cancer Research Centre is seeking expressions of interest from clinicians to take on up to 2 days/week of research sessions, to develop and lead research activity that will advance cancer clinical trials and translational cancer research in Wales.

- Clinician employed by NHS Wales who is a consultant in oncology, surgery and/or other cancer-related disciplines such as palliative care, general practice, etc. **OR** a senior member of other professional groups working in cancer, including nurses, allied health professionals, clinical scientists, or others who are in a position to lead cancer trials/translational research from Wales.
- Works in a cancer specialty; or cancer prevention, detection, diagnosis or cancer patient support form a substantial part of their NHS role.

Motivating those new to research: the associate PI role

What is an associate PI

- Six month in-work training run by NIHR opportunity for junior doctors, nurses, pharmacists and allied health professionals **not** currently working in research
- Aimed at developing practical research skills at start of research career
- Working on one NIHR portfolio trial, mentored by site principal investigator (PI)
- Completion of checklist and 'month one to six' online diary for certification

For one of my associate PIs, her reflections were as follows:

- Fantastic opportunity for individual to be exposed to research practice in supportive environment
- Opportunity to work with MDT – shared learning process
- Promotes clinical research
- May change career aspirations!
- Benefit to department – promotes research and may encourage engagement amongst staff

‘Mission’ of the Tackling Cancer Initiative

Mission: To enhance the quality of life and survival rates for cancer patients by providing access to better care, advanced research, and impactful collaboration among healthcare professionals, patients, industry and other communities.

Summing up

- Why research matters in health care ✓
- What about 'innovation' and 'quality improvement' ✓
- Case example using radiotherapy in prostate cancer management ✓
- What has motivated me to do research (and how we made it all happen) ✓
- Motivating others (using QI methodology) ✓
- What were the barriers and opportunities identified in 2012/2013 in the East of England ✓
- What were the opportunities and barriers identified in 2024/25 in NHS Wales ✓
- What we wanting to put in place in Wales: Tackling Cancer Initiative ✓
- Motivating and enabling both new and established researchers ✓

Thank you for listening!



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