Detection, Association? Surveillanciaes PSAfit in? Surveillanciaes PSAfit in? Where does PSAfit in? Surveillanciaes PSAfit in? Surveillanciaes PSAfit in? Where does PSAfit in?

Professor Caroline Moore MD FRCS(Urol)

NIHR Research Professor

Head of Urology, University College London

Consultant Urologist, University College London Hospitals Trust

Disclosures

- I am a urologist
- I work full time in prostate cancer
- I don't do radical prostatectomy

Disclosures

Grant funding

- National Institute for Health Research
- Medical Research Council
- Movember
- Prostate Cancer UK
- Cancer Research UK
- EAU Research Foundation

Commercial funding

- Trial funding Spectracure
- Proctor fees from Sonablate
- Speaker bureau fees from Astellas, Janssen, Bayer



Prostate cancer becomes most common cancer diagnosis in England

There were 55,033 diagnoses of prostate cancer in England in 2023 compared with 47,526 diagnoses of breast cancer

'Better and cheaper': the case for prostate cancer screening among black men

Decision over routine PSA testing is due at end of this month, though some feel the supporting data is unclear

RRC

Bigge in de

20 hours ago

Fergus Walsł

Medical Editor

TRANSFORM is now recruiting

If you're invited, please take part in the largest prostate cancer screening trial in 20 years





Prostate Cancer

- Most commonly diagnosed cancer in UK men
 - 55,485 UK men diagnosed in 2022
 - 1 in 8 UK men diagnosed in lifetime
 - 1 in 4 UK Black men diagnosed in lifetime

- Second commonest cause of cancer death
 - 13,237 UK deaths in 2022

Are you at risk of prostate cancer?



1 in 8

In the UK, about I in 8 men will get prostate cancer at some point in their lives.



Prostate cancer is the most common cancer in men in the UK.

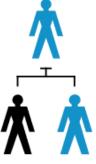
Over 50 years old

Prostate cancer mainly affects men over 50 and your risk increases with age.

The average age for men to be diagnosed with prostate cancer is between 65 and 69 years.

Family history and genes

You are two and a half times more likely to get prostate cancer if your father or brother has been diagnosed with it, compared to a man with no family history of prostate cancer.



Your risk of getting prostate cancer is higher if your mother or sister has had breast cancer.



Ethnicity



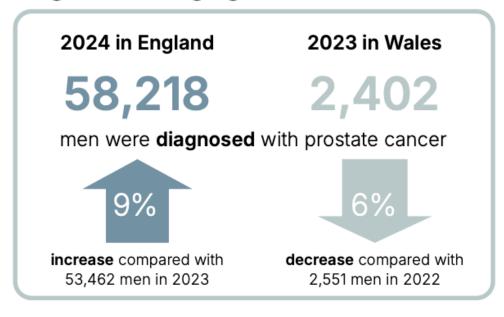
Black men are more likely to get prostate cancer than other men. In the UK, about I in 4 black men will get prostate cancer at some point in their lives. If you're black, you may be more likely to get prostate cancer if you're aged 45 or over.



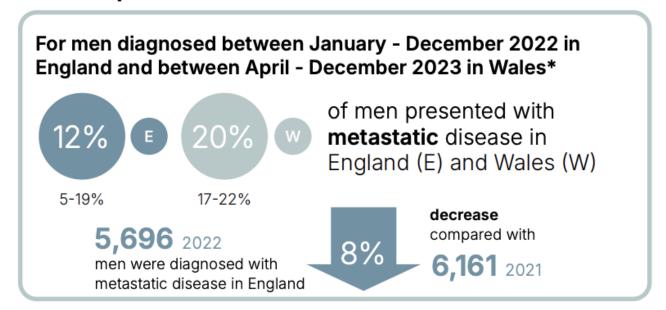
Speak to our Specialist Nurses 0800 074 8383* | prostatecanceruk.org Check your risk in 30 seconds: prostatecanceruk.org/risk-checker

^{1.} European Cancer Information System (ECIS) Data Explorer accessed 14/5/2024 at https://ecis.jrc.ec.europa.eu/index.php

Diagnosis & staging



Disease presentation



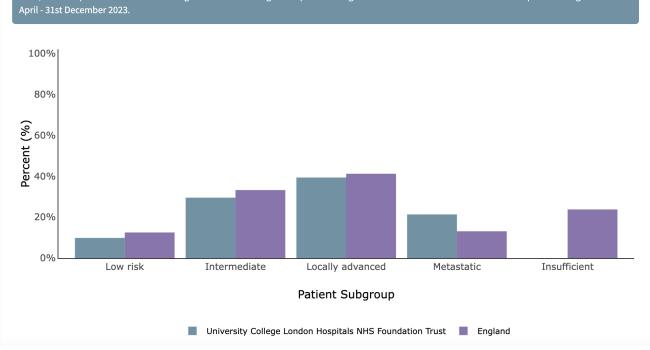


National Prostate Cancer Audit - State of the Nation Report (01 Jan 2022 - 31 Dec 2022)

Prostate cancer risk group







Treatment allocation

For men diagnosed between January - December 2022 in England and between April - December 2023 in Wales

Low-risk*, localised disease



High-risk/locally advanced disease





of men had radical treatments in England (E) and Wales (W)

Low-risk: T stage 1/2, Gleason ≤6, M/N 0 or missing = CPG 1 (Cambridge Prognostic Group 1)

Should we screen for prostate cancer?

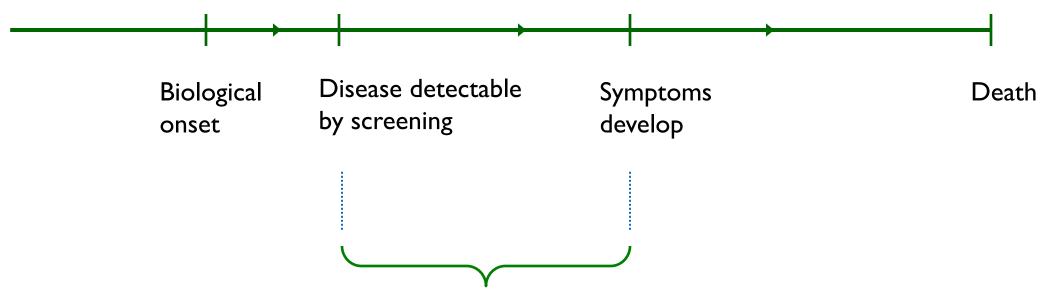
Screening

• "identifying apparently healthy people who may have an increased chance of a disease or condition....Individuals can then be offered more information, further tests or treatment as appropriate." UK National Screening Committee"

- Proactive approach by a screening provider (NHS) to people who are largely asymptomatic and not yet diagnosed with prostate cancer
- Does NOT rely on people approaching their GPs



How screening works



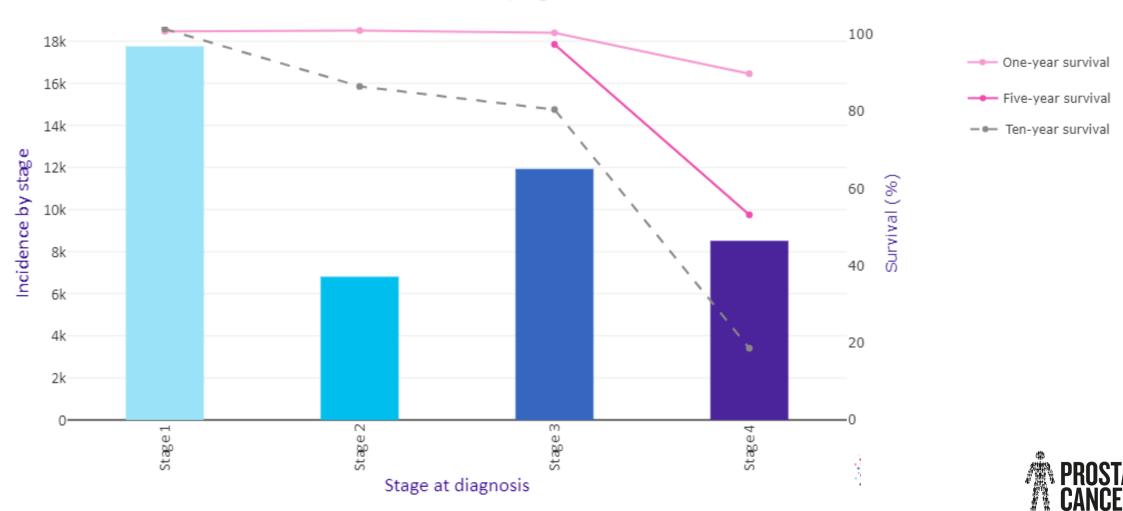
Finding cancers before a person notices a problem



Earlier Stage, Better Survival

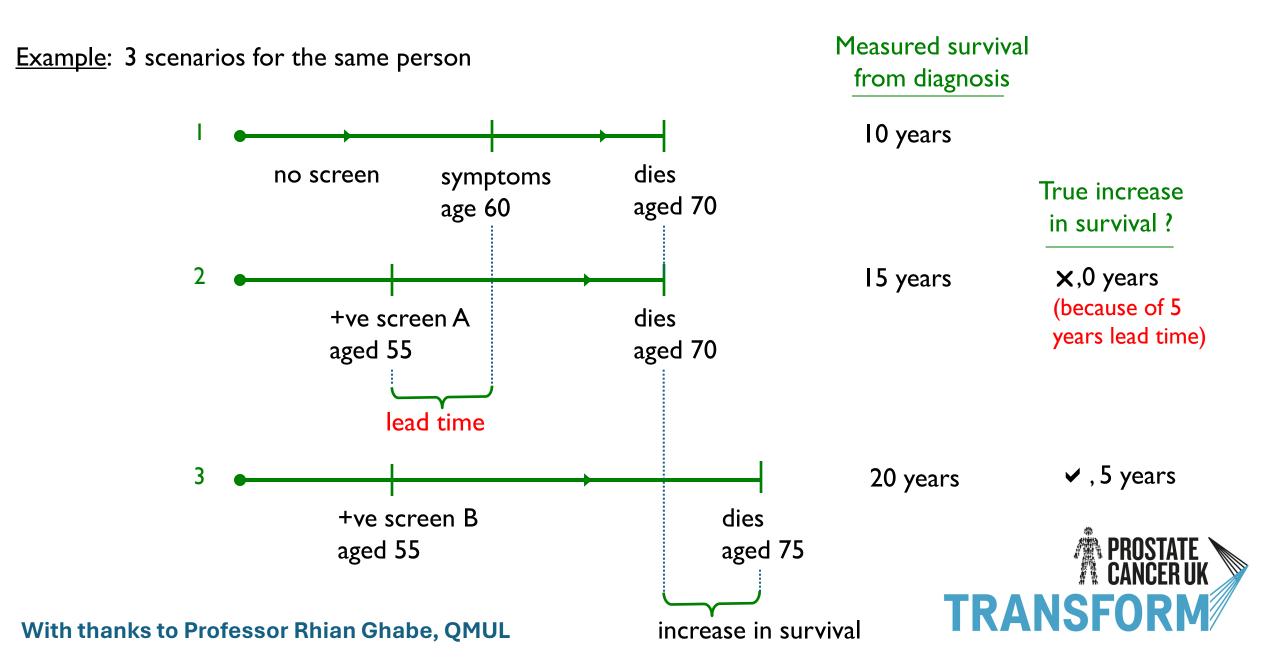
Incidence (2018) and Survival of Cancer Cases by Known Stage at Diagnosis,

Prostate cancer, England



Screening or early detection could save lives

Is there a benefit of earlier diagnosis?

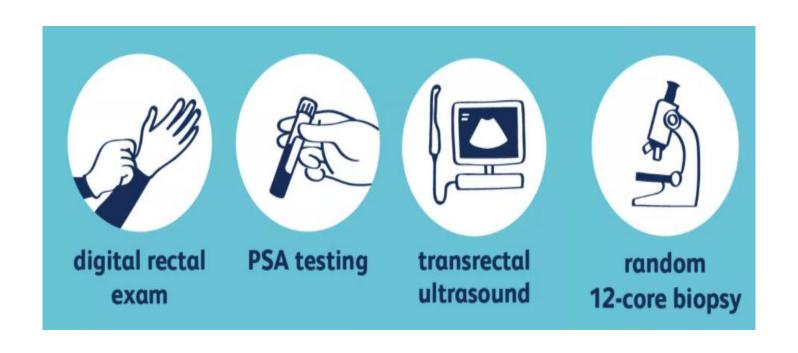


Potential harms of screening

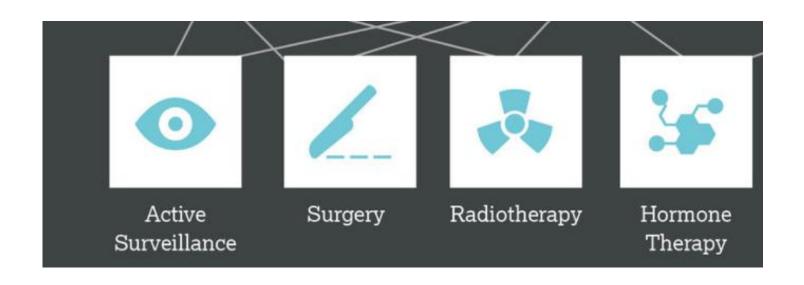
- Does it save lives?
 - Lead time bias know they have cancer for longer
 - Length bias screening picks up slow growing, better prognosis cancers
 - Selection bias healthy volunteers might be at lower risk of prostate cancer death due to other healthy behaviours
- Potential harms
 - Anxiety
 - Unnecessary invasive biopsies
 - Overdiagnosis
 - Overtreatment
- Costs
- Logistics



Traditional prostate cancer assessment



Traditional prostate cancer treatment



PSA as a screening test

JAMA | Original Investigation

Prostate-Specific Antigen Screening and 15-Year Prostate Cancer Mortality A Secondary Analysis of the CAP Randomized Clinical Trial

Richard M. Martin, BM, BS, PhD; Emma L. Turner, PhD; Grace J. Young, MSc; Chris Metcalfe, PhD; Eleanor I. Walsh, MSc; J. Athene Lane, PhD; Jonathan A. C. Sterne, PhD; Sian Noble, PhD; Peter Holding, MSc; Yoav Ben-Shlomo, MBBS, PhD; Naomi J. Williams, PhD; Nora Pashayan, MD, PhD; Mai Ngoc Bui, PhD; Peter C. Albertsen, MD; Tyler M. Seibert, MD, PhD; Anthony L. Zietman, MD; Jon Oxley, MD; Jan Adolfsson, MD; Malcolm D. Mason, MD; George Davey Smith, DSc; David E. Neal, MD; Freddie C. Hamdy, MD; Jenny L. Donovan, PhD; for the CAP Trial Group

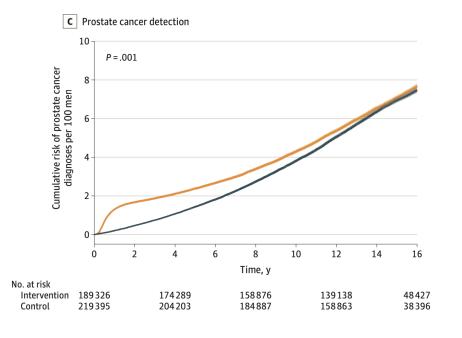
- Men aged 50 to 69 years at 573 primary care practices in England and Wales
- Patients enrolled 2002 2009 with follow up to 2021
- Randomised to invitation for single PSA test (195, 912) or no invitation (219,445)
 - Standard TRUS biopsy recommended if PSA ≥ 3ng/ml
- 98% of participants in control group were white
- Rate of low risk cancer increased in intervention group (2.2% vs 1.6%)
- Rate of high risk cancer reduced from 1.3% to 1.2% in intervention group

JAMA. 2024;331(17):1460-1470. doi:10.1001/jama.2024.4011 Published online April 6, 2024.

JAMA | Original Investigation

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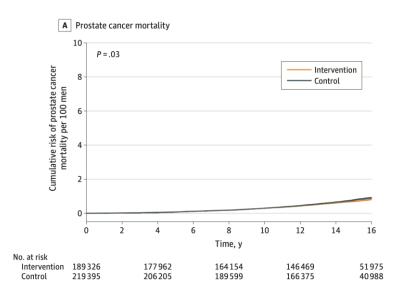
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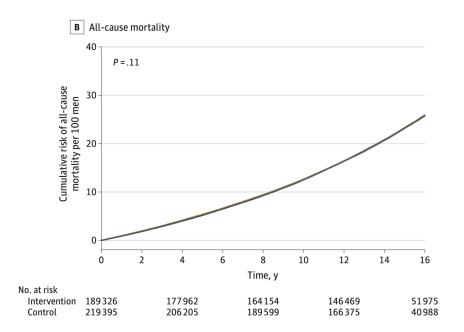


A single PSA test is not adequate for screening for prostate cancer

Screening reduced risk of death from prostate cancer (0.69% vs 0.78%; mean difference, 0.09%) but the effect was small.

JAMA. 2024;331(17):1460-1470. doi:10.1001/jama.2024.4011 Published online April 6, 2024.







European Study of Prostate Cancer Screening — 23-Year Follow-up

Monique J. Roobol, Ph.D.,¹ Ivo I. de Vos, M.D.,¹ Marianne Månsson, Ph.D.,² Rebecka A. Godtman, M.D., Ph.D.,² Kirsi M. Talala, Ph.D.,³ Elly den Hond, Ph.D.,⁴ Vera Nelen, M.D., Ph.D.,⁴ Arnauld Villers, M.D., Ph.D.,⁵ Gregoire Poinas, M.D.,⁶ Maciej Kwiatkowski, M.D., Ph.D.,⁷⁹ Stephen Wyler, Ph.D., M.D.,⁷⁸ Franz Recker, M.D., Ph.D.,⁷ Donella Puliti, Ph.D.,¹⁰ Giuseppe Gorini, M.D., Ph.D.,¹⁰ Marco Zappa, Ph.D.,¹⁰ Alvaro Paez, M.D.,¹¹ Marcos Lujan, M.D.,¹² Chris H. Bangma, M.D., Ph.D.,¹ Teuvo Tammela, M.D., Ph.D.,^{13,14} Fritz H. Schröder, M.D., Ph.D.,¹ Sebastiaan Remmers, Ph.D.,¹ Jonas Hugosson, M.D., Ph.D.,² and Anssi Auvinen, M.D., Ph.D.,¹⁵ for the ERSPC Investigators*

- ERSPC 23 year data on 162 389 men (55–69 yrs) from 1993 to 2020 or 23 years
- PSA testing with Hybritech assay systems (Beckman Coulter)
- Most centres used a cut off of 3ng/ml but
 - Italy used 4 ng/ml with DRE and TRUS for PSA 3-39.9 ng/ml
 - Finland added DRE for PSA 3 3.9 ng/ml until 1998 then $F:T \le 0.16$ after that
- 4 year interval in most but
 - Sweden & France 2 year interval
 - Belgium 7 year interval
- Average 2 screening visits per person

N Engl J Med 2025;393:1669-80. DOI: 10.1056/NEJMoa2503223

European Randomized Study of Icreening for Prostate Cancer

ESTABLISHED IN 1812

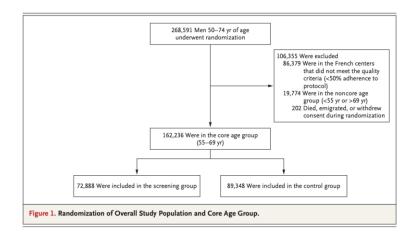
OCTOBER 30, 2025

VOL. 393 NO. 17

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- Harms of screening
 - 28% had a positive screening test & offered biopsy
- Over 3 in 4 biopsies (76%) were negative & hence 'unnecessary'
 - Over half of diagnoses were of low risk disease
 - Only 1 in 10 biopsies showed intermediate risk disease



N Engl J Med 2025;393:1669-80. DOI: 10.1056/NEJMoa2503223

ESTABLISHED IN 1812

OCTOBER 30, 2025

VOL. 393 NO. 17

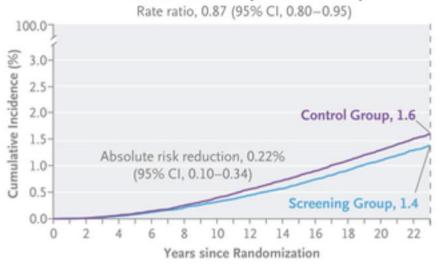
Prostate Cancer Diagnosis



Screening group had more Pca diagnoses 14% vs 12% 27 more diagnoses per 1000 men Risk ratio 1.3

> N Engl J Med 2025;393:1669-80. DOI: 10.1056/NEJMoa2503223

Prostate Cancer-Specific Mortality



Screening group had fewer Pca deaths 1.4% vs 1.6%

Risk ratio 0.87 intention to treat (13% reduction)
Risk ratio 0.84 if attended one screening visit
22% reduction in absolute risk of Pca death

ESTABLISHED IN 1812

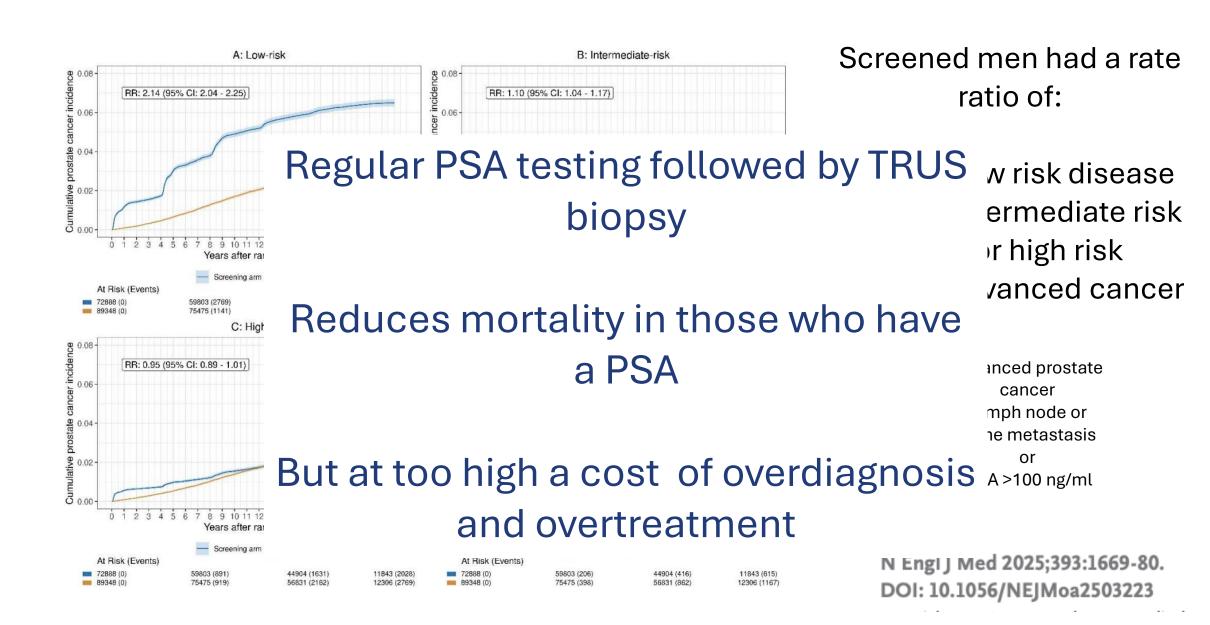
OCTOBER 30, 2025

VOL. 393 NO. 17

- Prostate cancer mortality
 - 1.4 vs 1.6% in screened vs control
- Other cause mortality
 - 49% at 23 years
 - No difference in screening vs control
- 30 x more likely to die of a non-prostate cancer cause
- Only 5.8% of men never screened in the intention to screen group
 - 7.4% one screening
 - 26% 2 screenings
 - 61% 3 or more screenings

N Engl J Med 2025;393:1669-80. DOI: 10.1056/NEJMoa2503223 Does PSA testing find the cancers that will kill?

Prostate cancer by EAU risk group at diagnosis



Things change over time....



October 2002



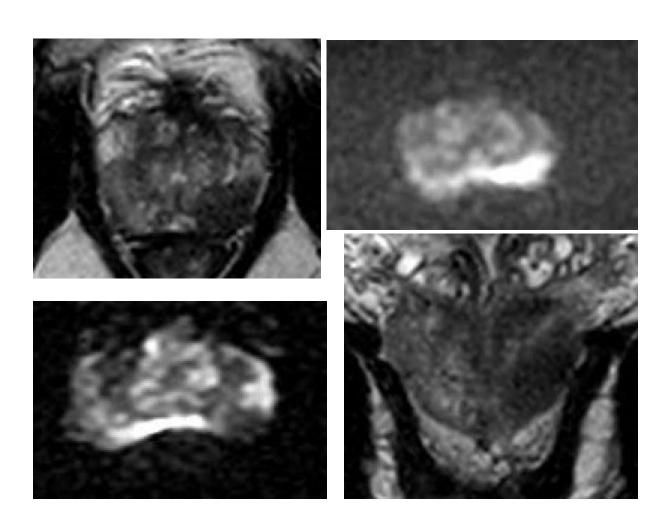




Now!



MRI can selectively detect significant cancer



We become what we behold. We shape our tools and then our tools shape us.

— Marshall McLuhan —

What we want from modern screening

Maximise benefit

- Reduce prostate cancer deaths by finding the most harmful cancers
- Use the best tests available
- Optimise prostate cancer treatment

Minimise harm

- Reduce overdiagnosis
 - Reduce anxiety
 - Reduce unnecessary re-testing
- Reduce over treatment





What happens when we use MRI to screen?





Design:

- Blinded, paired screen positive design
- Two screening centres

Participants:

- 411 men aged 50-69 years invited for screening
- 7 primary care practices + community recruitment

Screening Tests:

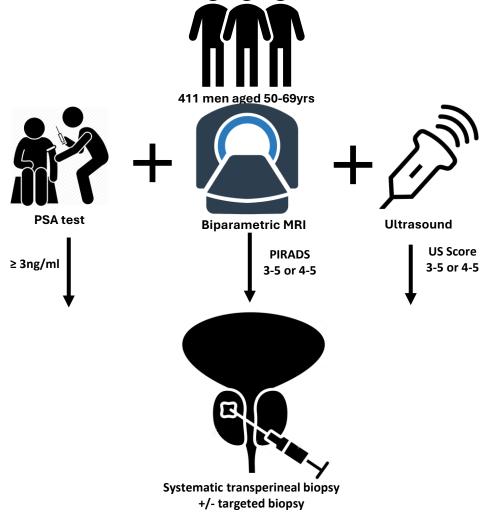
- MRI PIRADS Score + US Thresholds ≥3 OR ≥4
- PSA screen-positive: ≥3ng/ml

Reference test:

- Transperineal systematic 12-core biopsy +/targeting
- Clinically significant disease: Any Gleason ≥3+4

Blinding:

- Reporters blinded to other tests
- Participants blinded to indication for biopsy





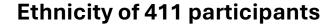


Design:

- Blinded, paired screen positive design
- Two screening centres



- 411 men aged 50-69 years invited for screening
- 7 primary care practices + community recruitment



Study	Ethnicity			
	White	Black	Asian	
CAP (2016)	98%	<2%	<2%	
PCPT (2006)	95.6%	3.2%	NR	
PCLO (2016)	85.0%	4.4%	4.0%	
PROSTAGRAM (2021)	39%	33%	23%	







With thanks to
David Eldred-Evans,
Prof Hashim Ahmed
& Imperial Prostate
team

Excludes ERSPC and STHLM3 which did not report ethnicity data.



PSA



3.0 ng/ml Biopsy rate 10% Sensitivity 41% Specificity 81%

bp-MRI



Biopsy rate 18%
Sensitivity 88% Specificity 51%



Biopsy rate 10.5% Sensitivity 65% Specificity 82%



relimagine

Design:

Men invited for screening MRI and blood test

 1 study centre (UCL) & 2 NHS centres (UCLH & Royal Free)

Participants:

- 6 primary care practices
- 2096 men aged 50-75 years invited for screening
- 303 completed both tests

Screening Tests:

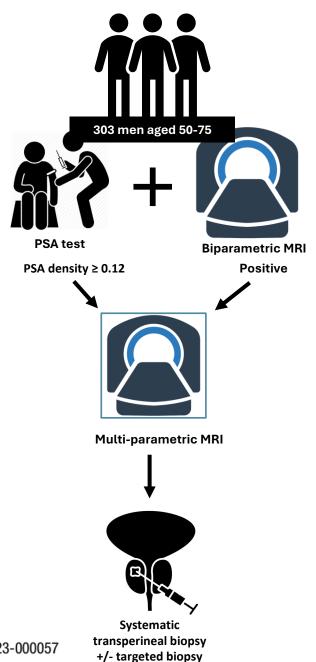
- MRI positive or negative
- PSA density : ≥ 0.12ng/ml²
- Referred for NHS assessment if screened positive

Reference test:

- Transperineal targeted + systematic cores
- Clinically significant disease: Any Gleason ≥3+4

Blinding:

- Reporters blinded to other tests
- Discussion with clinic nurse about biopsy with results



relimegine Response rates

	London population N= 797. 062	RelM	AGINE		
Ethnicit	Men aged 65-70 most likely to respond			2	
White					
Black					
Asian	Black men had 20% the response rate of				
Mixed		white men			
Other	13,572 (2%)	54 (3%)	14 (4%)		

1: Missing ethnicity data 490/2097 (23%) in the ReIMAGINE invited individuals

Our invitation profile matched the ethnicity profile of London

Our response rate was significantly lower in black men



^{2:} Missing ethnicity data 83/457 (18%) in the ReIMAGINE respondents

relimagine

PSA density



0.12 ng/ml 1 in 20 (16/303) had raised PSAD alone 1 in 4 clinically significant prostate cancer

bp-MRI





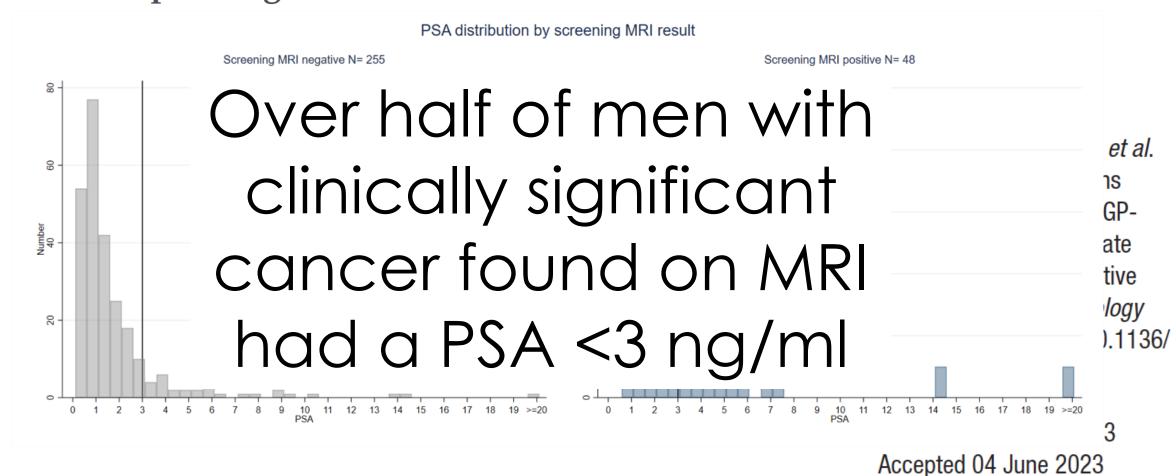
1 in 6 (48/303 or 16%) positive screen 1 in 2 clinically significant prostate cancer

NHS multiparametric
MRI
before biopsy decision

Open access Original research

BMJ Oncology

Prevalence of MRI lesions in men responding to a GP-led invitation for a



Next steps in screening in the UK

UK National Screening Committee

UK NSC requires robust evaluation to recommend that the UK government invests in national prostate cancer screening programme..... this means:

- Randomised controlled trial across the UK
- Making sure diverse population offered screening
- Making sure Black men who are at higher risk are represented
- Adequate proportion of those invited taking up the offer of screening
- Evaluating which is the best screening test



TRANSFORM Co-leads





Professor Hashim U. Ahmed

Head of Specialist Surgery

Chair & Professor of Urology

Imperial College London



Professor Rosalind Eeles
Professor of Oncogenetics
Institute of Cancer Research



Professor Mark Emberton
Professor of Interventional Oncology
University College London



Professor Rhian Gabe
Director of Barts CTU
Professor of Biostatistics & Clinical Trials
Queen Mary University of London



Professor Rakesh Heer
Chair & Professor in Urology
Imperial College London



Professor Caroline Moore

Head of Urology

NIHR Research Professor

University College London

TRANSFORM Aims

- Robust UK trial of modern screening approaches
- Assess acceptability, clinical & cost-effectiveness of different strategies
- Assess barriers and facilitators to equitable engagement across the population
- Create a data, imaging, histological and biological repository



TRANSFORM: 3 stage design

Stage 1 (3 years)

- Pilot 4 screening interventions
- Evaluate how to deliver pivotal trial assessing key processes and assumptions
- Short-term outcomes
- Develop bio-digital twin protocols

2

Stage 2 (6 years)

- Main trial of optimal intervention
- Medium-term clinical outcomes
- PROMS: quality of life.
- Costs and resources
- Create bio-digital twin

TRANSFROM Discovery

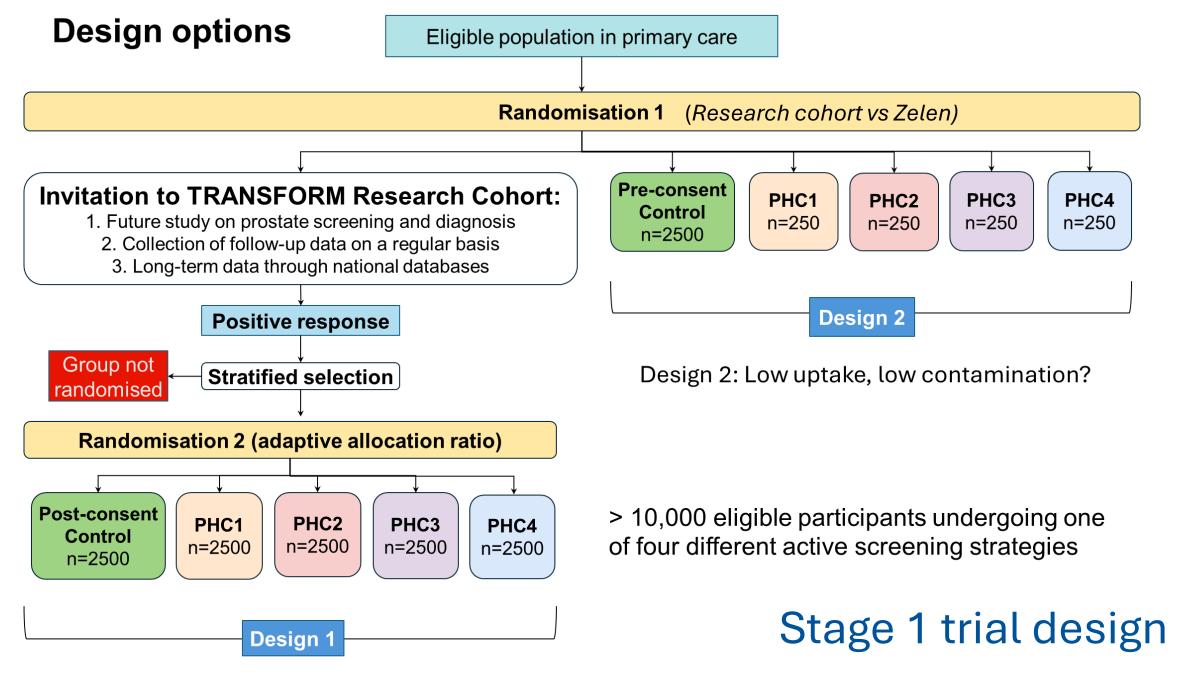
3

Stage 3 (10 years)

 Evaluate long-term primary outcomes through linkage to national databases

16,500 men

180,000 – 500,000 men



Design 1: High uptake, high contamination?

Prostate health checks

Arm 1: PSA 3 + MRI

PSA≥<u>3</u>ng/ml

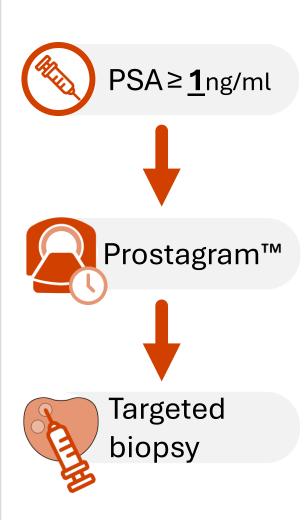


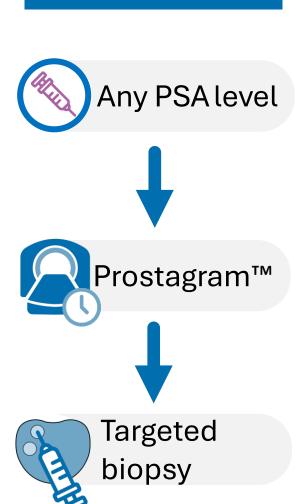
Prostagram™



Targeted biopsy

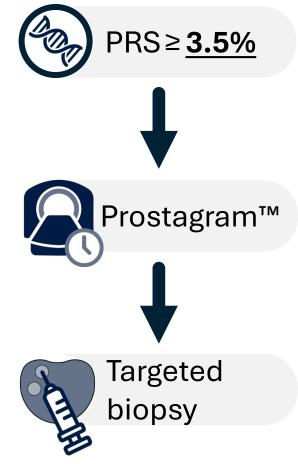
Arm 2: PSA 1 + MRI





Arm 3: MRI-only





EXPRESSION OF INTEREST SECONDARY SITES

Scotland (1)

NHS Lothian (Western General Hospital)

North West (4)

Lancashire Teaching Hospitals NHS Foundation Trust Mersey and West Lancashire Teaching Hospitals (Whiston Hospital) Clatterbridge Cancer Centre NHS Foundation Trust Mid Cheshire Hospitals NHS Foundation Trust

Midlands (4)

The Royal Wolverhampton NHS Trust University Hospitals Coventry and Warwickshire Northampton General Hospital NHS Trust Nottingham University Hospitals NHS Trust

Wales (1)

Wrexham Maelor Hospital

South West (1)

University Hospitals Plymouth NHS Trust (Derriford Hospital)

North East & Cumbria (0)

Yorkshire & Humber (3)

Airedale NHS Foundation Trust
Bradford Teaching Hospitals NHS Foundation Trust (Bradford Royal Infirmary)

East of England (1)

Norfolk and Norwich University Hospital

London (7)

Frimley Health NHS Foundation Trust (Wexham Park Hospital)
Croydon Health Services NHS Trust
London North West University Healthcare NHS Trust (Northwick Park)
Royal Free London NHS Foundation Trust
Homerton Healthcare NHS Foundation Trust University College London
Hospitals NHS Foundation Trust
Imperial College Healthcare NHS Trust

South East (2)

University Hospital Southampton NHS Foundation Trust University Hospitals Sussex NHS Foundation Trust









Stage 1 TRANSFORM

- Feasibility and piloting of 4 interventions
- Identification of the best PHC to take forward (maximum 2)
- Assess:
 - Rate of uptake of invitation across different populations (including black men and those in lowest 20% of index multiple deprivation, vulnerable groups eg learning disability)
 - Rates of PSA testing/MRI scans/Biopsies/Cancer diagnoses in the control group
 - Rates of uptake of the screening intervention across different arms



Active surveillance for prostate cancer

TRADITIONAL ACTIVE SURVEILLANCE

- Single protocol for follow up across a spectrum of risk of progression
- PSA and digital rectal examination done regularly
- Uptake of surveillance varies internationally & locally
 - 95% suitable men in UK
 - 60% suitable men US
- Protocols suggest regular biopsies but they are not always done
 - USA data 40% biopsy compliance at 2 years, <20% compliance after that
 - PRIAS data highest compliance 60% at year 4, sometimes <10%
- 1 in 4 men with no clinical change choose radical treatment as they don't like surveillance
- Men on active surveillance are 10 x as likely to die from heart disease than prostate cancer
- Must consider co-morbidities in men on active surveillance

Best Current Practice and Research Priorities in Active Surveillance for Prostate Cancer—A Report of a Movember Internation

Caroline M. Moore a,b,*, Lauren E. King c, John Withington a,b, Mahul B. Amin d,e, Mark Andrews f, Erik Briers g., Ronald C. Chen h., Francis I. Chinegwundoh ij, Matthew R. Cooperberg k,l,m, Iane Crowe n. Antonio Finelli o,p,q, Margaret I. Fitch, Mark Frydenberg, Francesco Giganti a,u, Masoom A. Haider v,w , John Freeman f, Joseph Gallo K, Stephen Gibbs f, Anthony Henry y , Nicholas James^z, Netty Kinsella aa,ab, Thomas B.L. Lam ac,ad, Mark Lichty^x, Stacy Loeb ae,af,ag Brandon A. Mahal^{ah}, Ken Mastris^{ai}, Anita V. Mitra^{aj}, Samuel W.D. Merriel^{ak,bb} Theodorus van der Kwast al. Mieke Van Hemelrijck aa. Nynikka R. Palmer am, an, ao. Catherine C. Paterson ap, aq, Monique J. Roobol ar, Phillip Segal as, James A. Schraidt at, Camille E. Short au,av, M. Minhaj Siddiqui aw, Clare M.C. Tempany ax,ay, Arnaud Villers az, Howard Wolinsky ba,bc, Steven MacLennan ac

Global effort to identify the top priorities in AS



UK & Europe Cancer Nurse (1) Clinical oncologist (1) Epidemiologist (2) GP (1) Lived experience (6) Radiation oncologist (1) Radiologist (1) Urologist (4)

Australia Behavioural scientist (1) Cancer nurse (1) GP (1) Urologist (1)

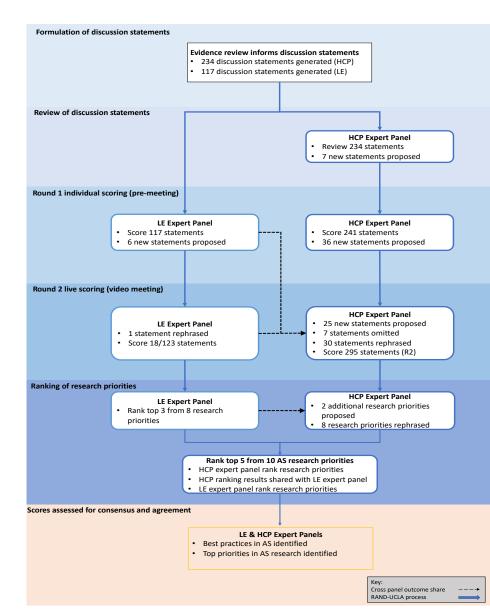
https://doi.org/10.1016/j.euo.2023.01.003

Lived Experience (LE) **Expert Panel**

· 12 participants

Healthcare Professional (HCP) **Expert Panel**

· 27 participants

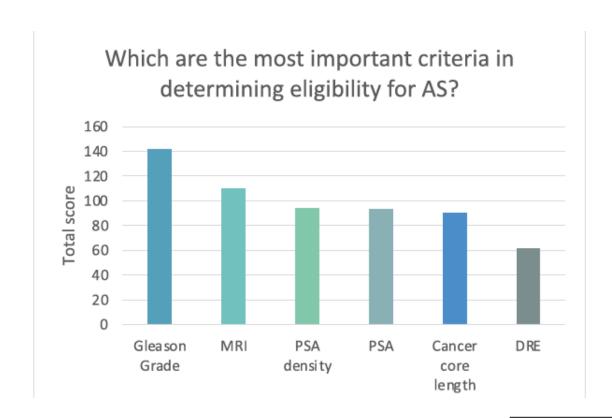


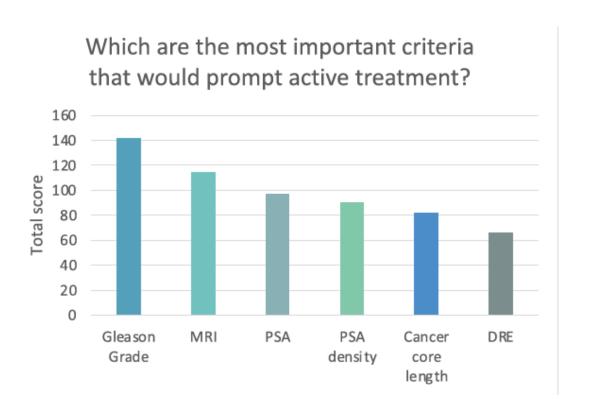
Best practice recommendations

- DRE can be omitted when MRI issued
- Consider omitting routine biopsy when PSA, MRI are stable
- Change in PSA should lead to MRI not biopsy or treatment
- Any change to active treatment should be based on a combination of a change in clinical factors and patient discussion
- Men with clinical parameters suitable for AS but may be at risk of psychological harm should be offered psychological support rather than radical treatment

Best Current Practice and Research Priorities in Active Surveillance for Prostate Cancer—A Report of a Movember International Consensus Meeting







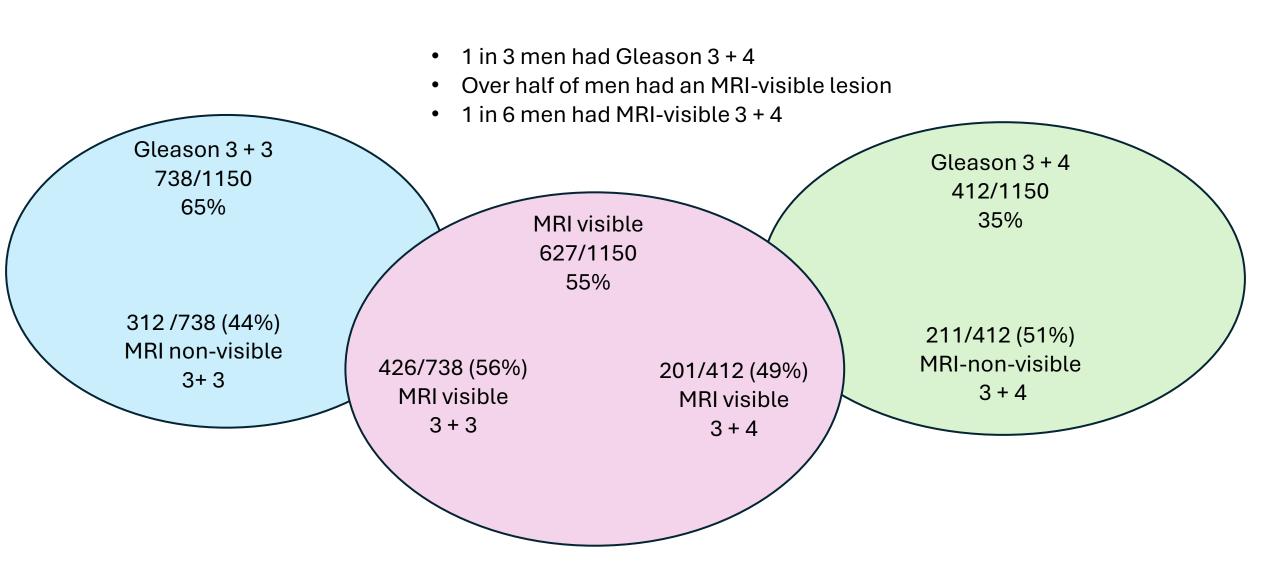
UCLH active surveillance

- Determine risk factors before enrolment on AS
 - PSA & PSA density
 - MRI visible with Likert 4/5
 - Biopsies Gleason score (including % pattern 4) and maximum cancer core length
- Repeat MRI and /or biopsy if discordant results
- Assess for changes according to baseline risk
- Use PSA and MRI
- Biopsy during surveillance if
 - Change on MRI suggests a change in risk
 - PSA rising and not explained by growth of the whole prostate on MRI

UCLH baseline data

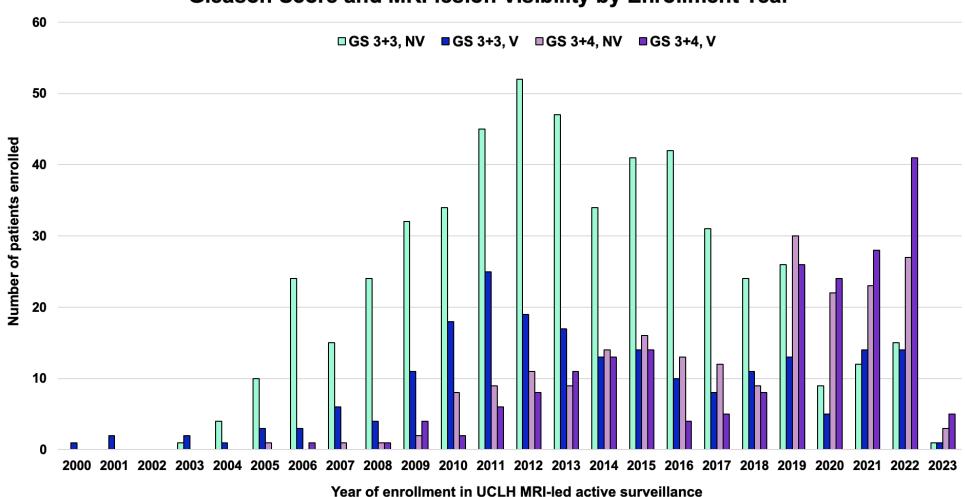
	All patients	Gleason Sco	re and visible lesion	on on baseline biop	sy and MRI*
		3+3, NV	3+3, V	3+4, NV	3+4, V
n	1,150	523	215	211	201
Age at diagnosis (yr), (SD)	60 (0)	σ 1 (7)	64 (8)	62 (8)	05 (0)
PSA at baseline (ng/ml), (IQR)	6 (4.3-8.1)	5.9 (4.2-7.6)	6.3 (4.6-9.0)	6 (4.2-8.1)	6.1 (4.4-8.5)
Prostate volume at baseline MRI (cc)	45.7 (02.7 62.4)	49 (35-67)	41.9 (32.3-61.2)	45 (32-63)	20 (20 00)
PSAD at baseline MRI (ng/ml²)	0.12 (0.09-0.18)	0.12 (0.08-0.17)	0.14 (0.1-0.2)	0.13 (0.09-0.18)	0.13 (0.1-0.21)
Entry biopsy					
No. of cores	14 (11-23)	12 (10-22.5)	13 (11-18)	16 (12-27)	14 (11-21)
No. of positive cores	2 (1-4)	2 (1-3)	2 (1-3)	3 (2-4.8)	4 (2-6)
MCCL**	2 (1-5)	1.5 (1-3)	2.25 (1-5)	3 (2-4)	4.5 (3-7)
Visible lesion on baseline scan	416 [36.2]	0	215 [100]	0	201 [100]
Highest Likert score on baseline MRI					
2	323 [28.1]	259 [49.5]	0	63 [29.9]	0
3	412 [35.8]	264 [50.5]	0	148 [70.1]	0
4	395 [34.3]	0	210 [97.7]	0	185 [92]
5	21 [1.8]	0	5 [2.3]	0	16 [8]

Gleason score & MRI visibility at Baseline



Risk by Gleason score & MRI visibility over time

Gleason Score and MRI-lesion Visibility by Enrollment Year



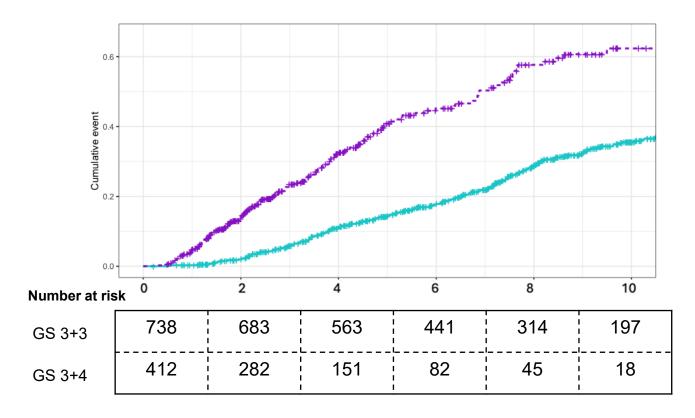
Whole cohort outcomes of MRI-led risk adapted active surveillance

- Event free survival for the cohort
 - 3 years 87%
 - 5 years 76%
 - 10 years 53%
- Biopsy rate 487/1150 (42%) had a further biopsy on AS
- Histological upgrade to 4 + 3 rare: 67/1150 (6%)
- Only 3% (30 patients) chose treatment despite stable parameters
 - Reduced from 20% in traditional surveillance
- 1 in 3 have had treatment

Can we personalise the outcomes for men considering active surveillance?

Using Gleason score to risk stratify

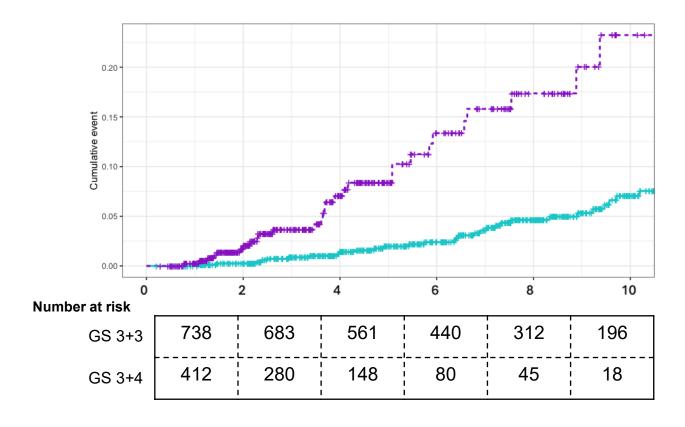
Active treatment



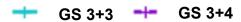
	5 year treatment rate (%)
Overall cohort	22
3 + 3	14.3
3 + 4	41.9



Histological progression to Gleason $\geq 4 + 3$

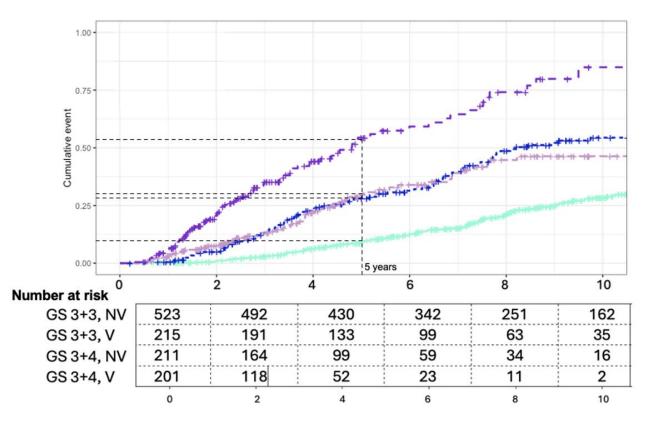


	5 year detection of Gleason ≥ 4 + 3 (%)
Overall cohort	3.7
3 + 3	2.0
3 + 4	8.4



Adding MRI-visibility to Gleason score to risk stratify

Active treatment

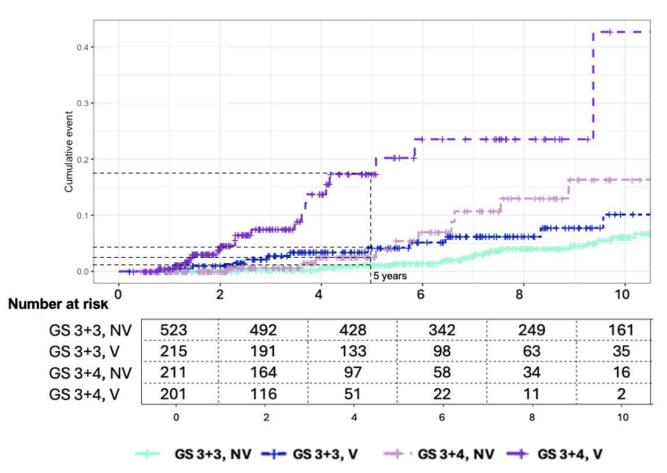


GS 3+3, NV --- GS 3+3, V

	5 year active treatment(%)
Overall cohort	22
Non-visible 3 + 3	9
MRI-visible 3 + 3	28
Non-visible 3 + 4	30
MRI-visible 3 + 4	55

→ GS 3+4, NV → GS 3+4, V

Histological progression to Gleason $\geq 4 + 3$

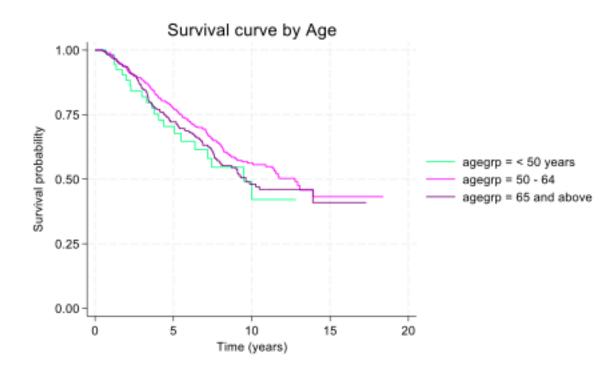


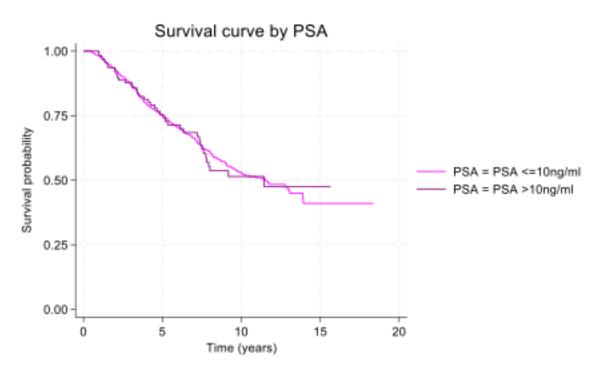
	5 year histological progression to Gleason ≥ 4 + 3 (%)
Overall cohort	3.7
Non-visible 3 + 3	1.2
MRI-visible 3 + 3	4.3
Non-visible 3 + 4	2.5
MRI-visible 3 + 4	17.4

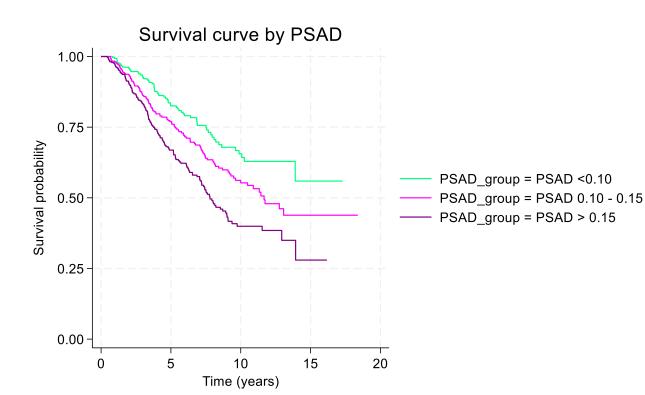
With particular thanks to Dr Cameron Englman

Could we personalize active surveillance by further risk stratification?

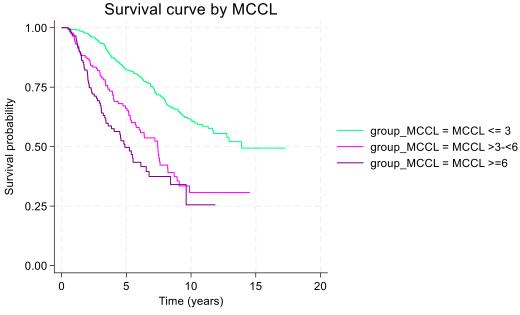
Do age or PSA predict the likelihood of treatment in an MRI-led cohort?







Adding in PSA density and maximum cancer core length



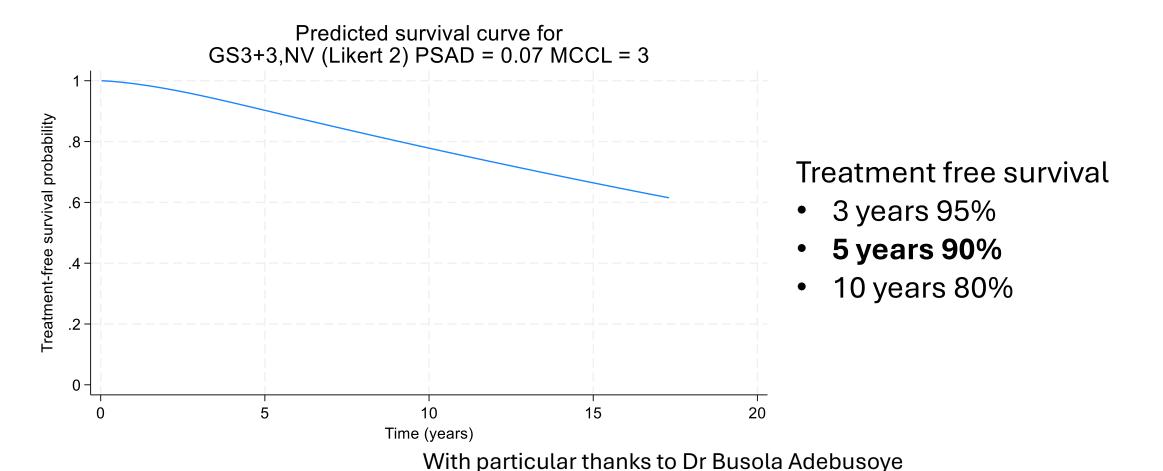
Multi-variable analysis of risk factors in active surveillance

Risk factor	Cox model			
	Hazard ratio (confidence interval)			
Gleason grade & MRI visibility				
GS 3+3 NV	Ref			
GS 3+3 V	2.30(1.65 - 3.20)			
GS 3+4 NV	2.17(1.53 – 3.09)			
GS 3+4 V	4.04(2.84-5.74)			
PSA density				
PSAD (<0.10)	Ref			
PSAD (0.10-0.15)	1.35(0.97 -1.89)			
PSAD (PSAD >0.15)	1.76(1.27-2.43)			
Maximum cancer core length				
MCCL < 4	Ref			
MCCL 4-<7	1.61(1.22-2.14)			
MCCL 7 -<10	1.97(1.29-3.00)			
MCCL > 10	2.73(1.50-4.94)			

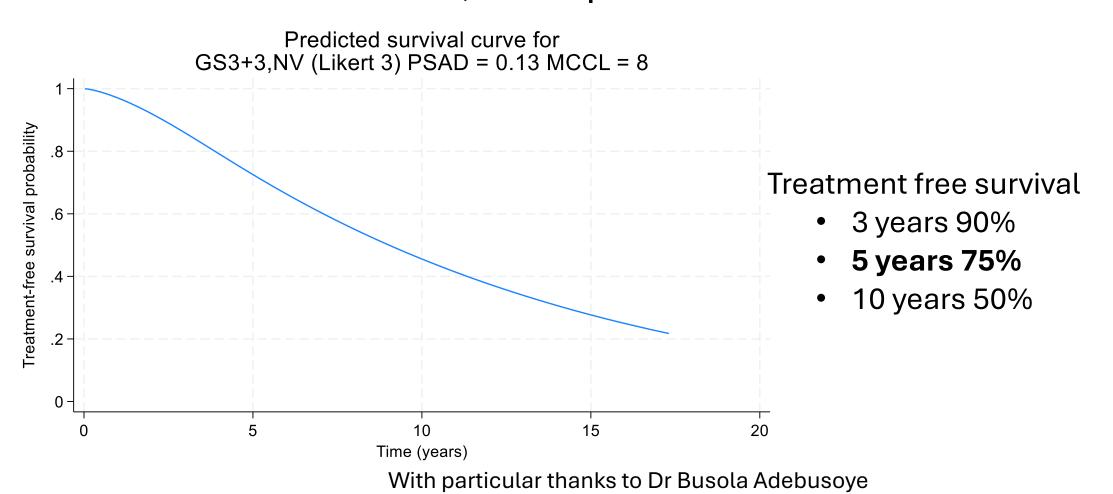
Development of a model to predict treatment free survival

With particular thanks to Dr Busola Adebusoye

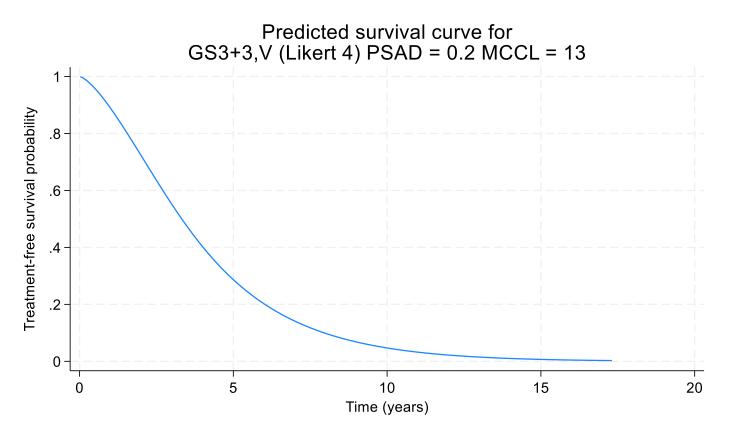
Mr Lenny Low Risk 3mm Gleason 3 + 3 Not MR visible (Likert 2) PSA 4, 60 ml prostate PSA density 0.07



Mr Alan also Low risk 8mm 3 + 3 Not MRI visible (Likert 3) PSA 10.4, 80 ml prostate PSAD 0.13



Mr Victor Intermediate risk 13mm Gleason 3 + 3 MRI visible (Likert 4) PSA 12, 60 ml prostate PSAD 0.2

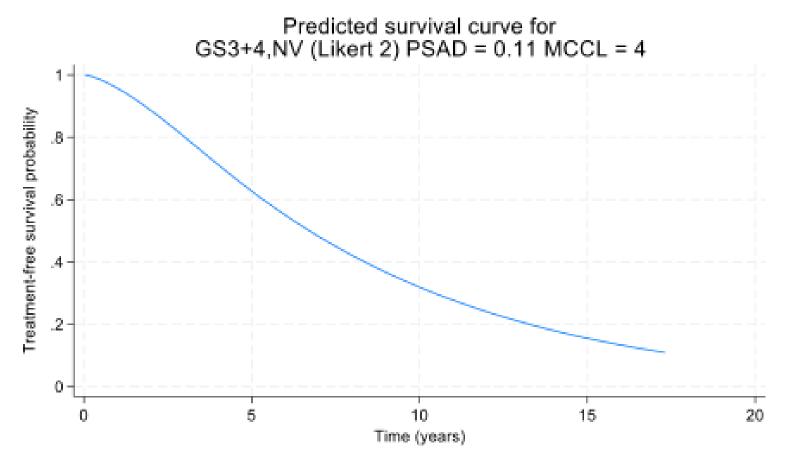


Treatment free survival

- 3 years 60%
- 5 years 25%
- 10 years <10%

With particular thanks to Dr Busola Adebusoye

Mr Norman Another Intermediate risk 4mm Gleason 3 + 4 Not MRI visible (Likert 2) PSA 5, prostate volume 45 mls, PSA density 0.11

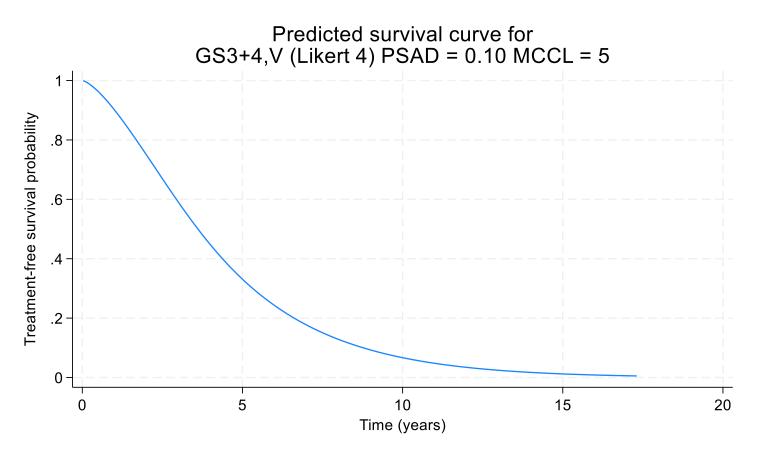


Treatment free survival

- 3 years 80%
- 5 years 60%
- 10 years 33%

With particular thanks to Dr Busola Adebusoye

Mr Vince Increasing risk 5mm 3 + 4 MRI Visible (Likert 4) PSA 5, 50 ml prostate PSAD 0.10



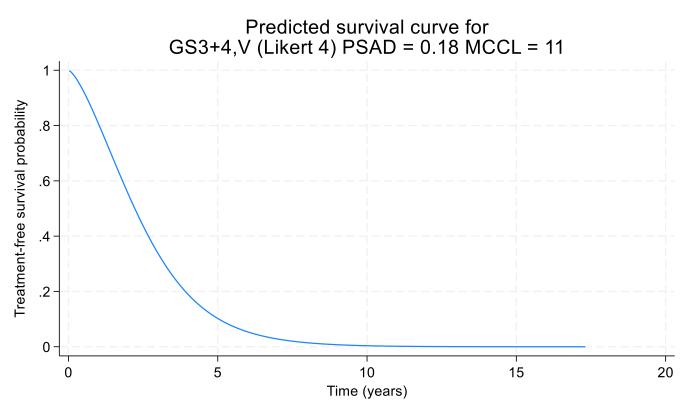
UCLH treatment free survival

- 3 years 60%
- 5 years 30%
- 10 years 10%

With particular thanks to Dr Busola Adebusoye

Mr Harry Higher risk

11mm Gleason 3 + 4 MRI visible (Likert 4) 50 m l prostate PSA 9 PSAD 0.18



UCLH Treatment free survival

- 50% at 3 years
- 10% at 5 years
- Negligible at 10

** Not recommended for AS

With particular thanks to Dr Busola Adebusoye

		Not visible on MRI (Likert 1-3)						Visible on MRI (Likert 4/5)					
		PSA density						ry (ng/ml/ml)					
		<0.1	0.1-0.12	0.12- 0.15	0.15 – 0.2	>0.2	<0.1	0.1-0.12	0.12-0.15	0.15 – 0.2	>0.2		
Histology	MCCL (mm)												
	<u><</u> 3	Lenny 90%											
Gleason 3 + 3	> 3 to <6												
	≥ 6 to < 10			Alan 75%									
	> 10									Victor 25%			
Gleason 3 + 4	<u><</u> 3												
	> 3 to <6		Norman 60%					Vince 30%					
	≥ 6 to <10												
	> 10									Harry 10%			

4 factor risk stratification for 5 year TFS

		Not visible on MRI (Likert 1-3)					Visible on MRI (Likert 4/5)				
		PSA density (ng/ml/ml)									
Histology	Maximum cancer core length (mm)	<0.1	0.1- 0.12	0.12- 0.15	0.15 – 0.2	>0.2	<0.1	0.1- 0.12	0.12- 0.15	0.15 – 0.2	>0.2
	<u><</u> 3	0.91	0.90	0.87	0.87	0.84	0.81	0.79	0.73	0.72	0.66
Gleason 3 + 3	> 3 and <6	0.87	0.86	0.82	0.81	0.77	0.73	0.70	0.62	0.61	0.54
Gleasons+3	≥ 6 and < 10	0.83	0.81	0.75	0.74	0.69	0.64	0.60	0.51	0.49	0.42
	> 10	0.77	0.75	0.68	0.67	0.61	0.55	0.51	0.4	0.39	0.31
	<u><</u> 3	0.82	0.80	0.74	0.73	0.68	0.70	0.67	0.59	0.57	0.51
Gleason 3+4	> 3 and <6	0.74	0.71	0.64	0.62	0.56	0.59	0.55	0.45	0.44	0.36
Gleason 3+4	≥ 6 and < 10	0.65	0.63	0.53	0.51	0.44	0.47	0.43	0.33	0.31	0.24
	> 10	0.57	0.53	0.42	0.41	0.34	0.36	0.32	0.22	0.2	0.14

MEASURED 1 MEASURED 2 MEASURED 3

Summary

- Risk-adapted active surveillance makes sense
- When using an MRI-led pathway for diagnosis it makes sense to use an MRI-led, risk adapted pathway for monitoring
- Consider the risk factors to be:
 - Gleason score
 - MRI-visibility
 - Maximum cancer core length
 - PSA density (not PSA < or > 10 ng/ml)
- Always remember to assess the whole person not just the MRI!

Let's move onto treatment...

Focal therapy for prostate cancer

A small treatment for a small cancer

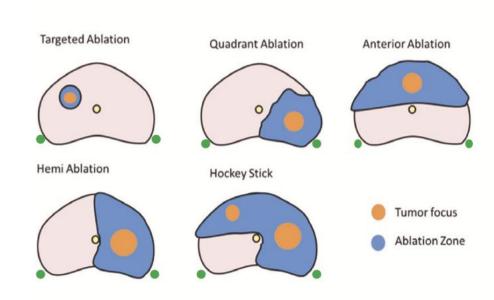


Risk of cancer progression

Risks of radical treatment

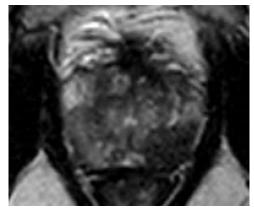
What do we mean by focal therapy?

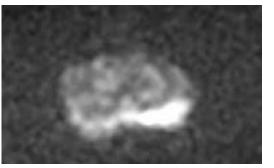
- Targeted to the index lesion
 - Gleason 3 + 4 or 4 + 3
 - Visible on MRI
 - With an adequate margin
- Using any modality
 - Heat
 - Ice
 - Electrical disruption
 - Others (laser, photodynamic therapy)

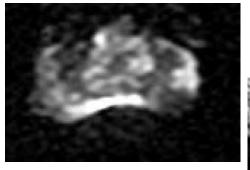


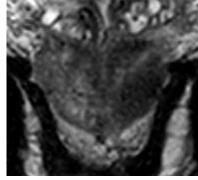
Typical case

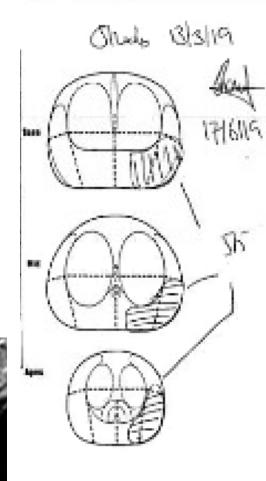
- MRI March 2019
- 12mm 3 + 4 on biopsy
- Left focal HIFU July 2019
- 4cm, 3cm, 3cm
- Excellent Uchida changes
- Day surgery procedure
- Catheter for 5 days

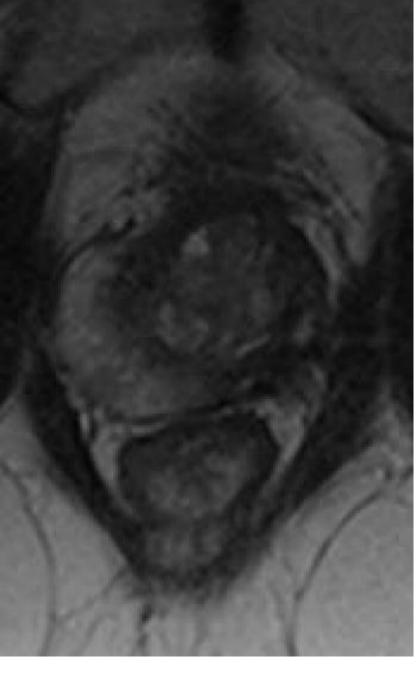






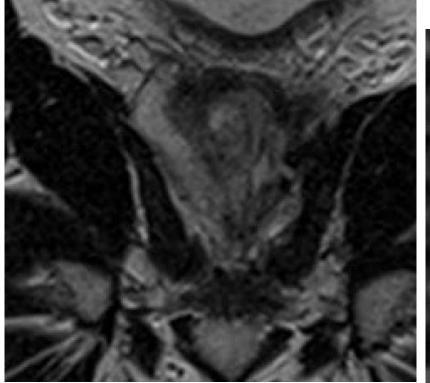


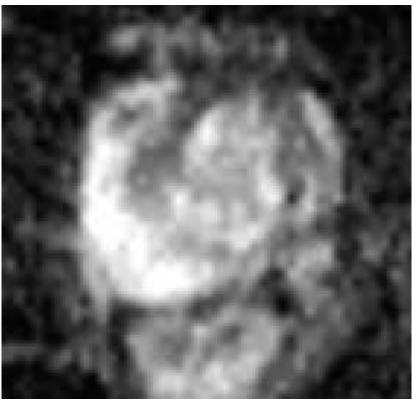




12 Month follow up

- PSA reduced from 6.9 to 1.9
- Good erections with no tablets
- No urinary symptomsNon-suspicious MRI





5 year follow up

- PSA risen to 2.4
- Non-suspicious MRI



High Intensity focussed ultrasound (HIFU)

- Most widely used energy source for focal therapy of localized prostate cancer.
- Ideal application: treatment of posterolaterally located lesions, due to favorable accessibility and energy delivery profile.
- Limitations: less effective and technically challenging for apical lesions, where treatment precision is constrained by anatomical proximity to the sphincter and urethra.

Transrectal Systems:

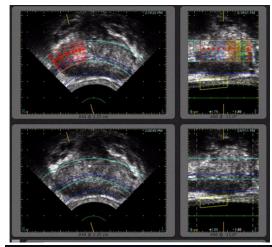
- Sonablate® (SonaCare Medical, USA)
- Focal One® (EDAP TMS, France)

Transurethral Systems:

- TULSA-PRO® (Profound Medical, Canada)

Emerging:

MRI-guided transrectal HIFU (Insightec ExAblate®)







Cryotherapy

Medium and some high risk prostate cancers

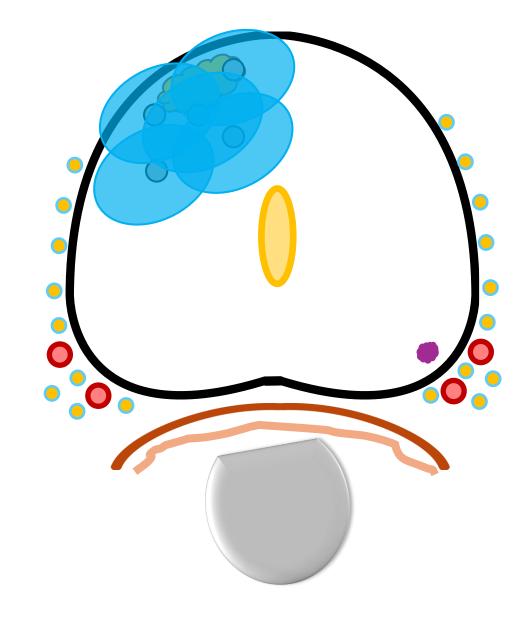
Cryotherapy

Ultrasound probe in rectum to guide treatment

Needles inserted through skin behind scrotum (perineal)

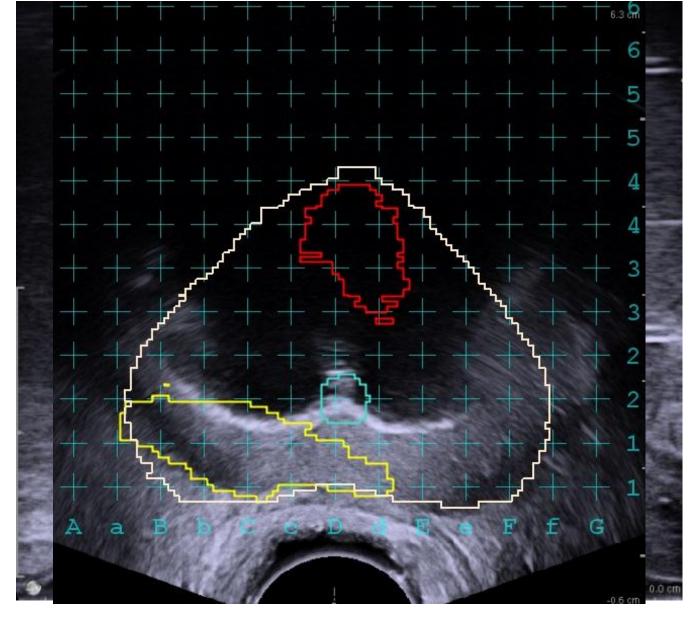
Each needle grows an iceball down to temperatures of at least -40°C

Can be repeated



With thanks to Professor Hashim Ahmed, Imperial College London

Cryotherapy



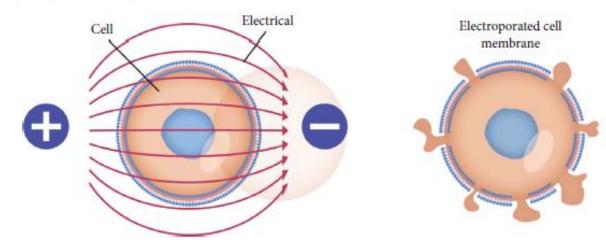
With thanks to Professor Hashim Ahmed, Imperial College London

Irreversible electroporation (IRE)

IRE is an ablative treatment for prostate cancer

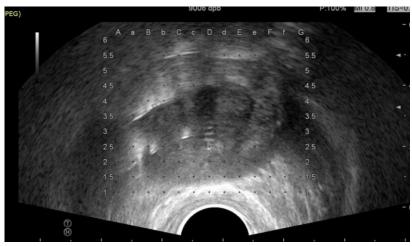
- Direct current is applied to the target area electrodes (needles) via brachy grid
- Cell membranes are depolarised
- Excessive permeability leads to cell death by apoptosis
- HIFU and Cryo rely instead upon thermal injury and necrosis

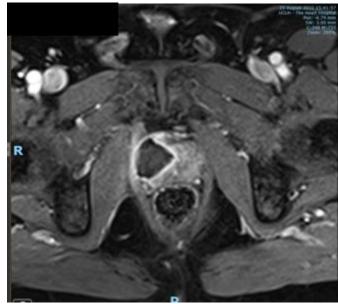
Fig. 2 IRE is based on the principle of electroporation.



IRE

- Functional and oncological outcomes similar to HIFU/Cryo
- Short procedures (<60 mins)
- Short learning curve
 - Fusion if required
 - Energy delivery less dependent on USS skill
 - Non thermal ablation may offer advantage
- Harder at extreme apex, pacemakers
- ARC registry for prospective data collection





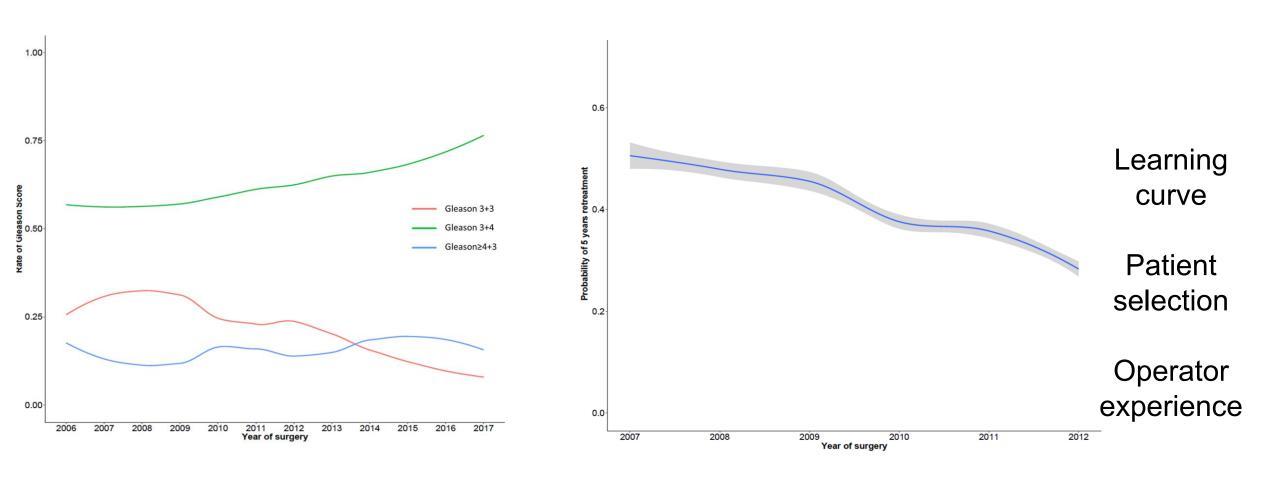
Medium-term oncological outcomes in a large cohort of men treated with either focal or hemi-ablation using high-intensity focused ultrasonography for primary localized prostate cancer



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Armando Stabile*<sup>†‡</sup>, Clement Orczyk*<sup>‡</sup>, Feargus Hosking-Jervis<sup>‡</sup>, Francesco Giganti<sup>‡§</sup>, Manit Arya*<sup>‡</sup>, Richard G. Hindley*, Louise Dickinson<sup>§</sup>, Clare Allen<sup>§</sup>, Shonit Punwani<sup>§</sup>, Charles Jameson<sup>¶</sup>, Alex Freeman<sup>¶</sup>, Neil McCartan<sup>‡</sup>, Francesco Montorsi<sup>†</sup>, Alberto Briganti<sup>†</sup>, Hashim U. Ahmed**<sup>††</sup>, Mark Emberton*<sup>‡</sup> and Caroline M. Moore*<sup>‡</sup>
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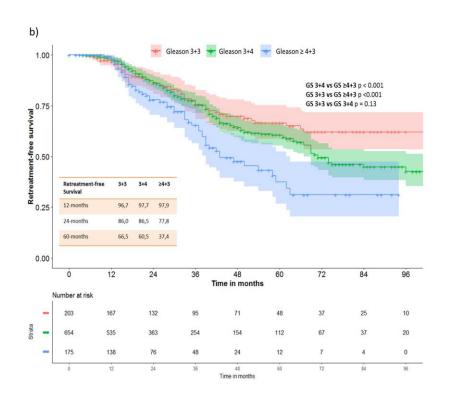
- 1032 consecutive men treated by UCL team at UCLH (NHS) and London Urology Associates (PP)
- 2005-2017
- Follow up of men who are deemed stable with GP
- Follow up of higher risk men in clinic
- 80% 3 + 4
- 3.8% of men in cohort went on to radical treatment

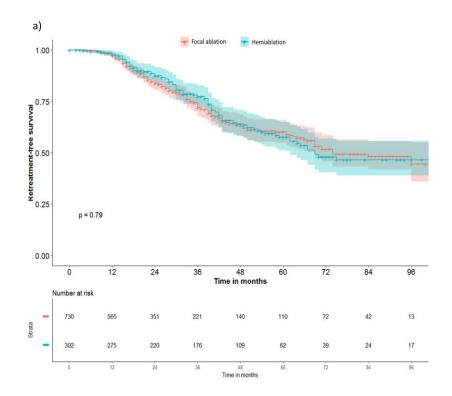
Who gets focal HIFU?



5 year retreatment rates reduced over time

What predicts the need for additional treatment?





Effect of Gleason grade

Focal vs hemi-ablation

Cancer Control Outcomes Following Focal Therapy Using Highintensity Focused Ultrasound in 1379 Men with Nonmetastatic Prostate Cancer: A Multi-institute 15-year Experience

```
Deepika Reddy <sup>a,b,*</sup>, Max Peters <sup>c</sup>, Taimur T. Shah <sup>a,b</sup>, Marieke van Son <sup>c</sup>, Mariana Bertoncelli Tanaka <sup>b</sup>, Philipp M. Huber <sup>d</sup>, Derek Lomas <sup>e</sup>, Arnas Rakauskas <sup>f</sup>, Saiful Miah <sup>g</sup>, David Eldred-Evans <sup>a</sup>, Stephanie Guillaumier <sup>h,i</sup>, Feargus Hosking-Jervis <sup>a</sup>, Ryan Engle <sup>a</sup>, Tim Dudderidge <sup>j</sup>, Richard G. Hindley <sup>k,l</sup>, Amr Emara <sup>k,x</sup>, Raj Nigam <sup>m,n</sup>, Neil McCartan <sup>h,i</sup>, Massimo Valerio <sup>f</sup>, Naveed Afzal <sup>o</sup>, Henry Lewi <sup>p</sup>, Clement Orczyk <sup>h,i</sup>, Chris Ogden <sup>q</sup>, Iqbal Shergill <sup>r</sup>, Raj Persad <sup>s</sup>, Jaspal Virdi <sup>t</sup>, Caroline M. Moore <sup>h,i,u,v</sup>, Manit Arya <sup>b,h,i</sup>, Mathias Winkler <sup>a,b</sup>, Mark Emberton <sup>h,i,u,v,†</sup>, Hashim U. Ahmed <sup>a,b,v,w,†</sup>
```

- HIFU Evaluation and Assessment of Treatment (HEAT) registry
- 1379 primary focal patients across 13 UK centres 2005 -2020
- Median follow up 32 m overall
 - For >5 years, median follow up 82 m
- 2nd focal treatment 1 in 5
- Radical treatment 1 in 15
- PSA 3 m for year 1, then 6m
- MRI 1 year and periodically after, biopsy as needed

Cancer Control Outcomes Following Focal Therapy Using Highintensity Focused Ultrasound in 1379 Men with Nonmetastatic Prostate Cancer: A Multi-institute 15-year Experience

Deepika Reddy ^{a,b,*}, Max Peters ^c, Taimur T. Shah ^{a,b}, Marieke van Son ^c,
Mariana Bertoncelli Tanaka ^b, Philipp M. Huber ^d, Derek Lomas ^e, Arnas Rakauskas ^f,
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Ryan Engle ^a, Tim Dudderidge ^j, Richard G. Hindley ^{k,l}, Amr Emara ^{k,x}, Raj Nigam ^{m,n},
Neil McCartan ^{h,i}, Massimo Valerio ^f, Naveed Afzal ^o, Henry Lewi ^p, Clement Orczyk ^{h,i},
Chris Ogden ^q, Iqbal Shergill ^r, Raj Persad ^s, Jaspal Virdi ^t, Caroline M. Moore ^{h,i,u,v},
Manit Arya ^{b,h,i}, Mathias Winkler ^{a,b}, Mark Emberton ^{h,i,u,v,†}, Hashim U. Ahmed ^{a,b,v,w,†}

Overall failure free survival 69% at 7 years

Failure defined as

- evidence of cancer requiring whole-gland salvage treatment/ 3rd focal therapy
- systemic treatment
- prostate cancer metastases
- prostate cancer–specific death

Radical treatment free survival 73% at 7 years

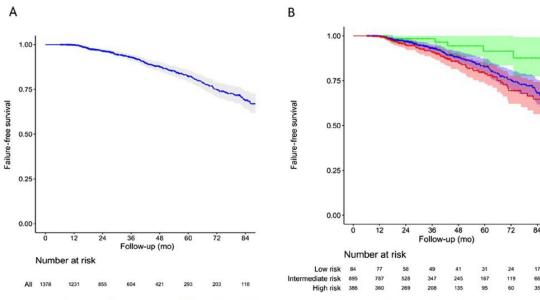


Fig. 1 – Kaplan-Meier curves of failure-free survival (FFS) with 95% confidence intervals. FFS is defined as transition to whole-gland salvage treatment or third focal therapy treatment, systematic treatment, and/or development of prostate cancer metastases and/or prostate cancer-specific death for (A) all patients with at least 6 mo of follow-up and (B) 1365 patients stratified per D'Amico low-risk (green line), intermediate-risk (blue line), and high-risk (red line) group (log-rank analysis of D'Amico intermediate- vs high-risk disease p = 0.3).

Focal therapy compared to radical prostatectomy for non-metastatic prostate cancer: a propensity score-matched study

Taimur T. Shah plane Reddy Peters Park Peters Park Peters Park Peters Na Hyun Kim² · Enrique Gomez Gomez Saiful Miah⁵ · David Eldred Evans Peters S. Na Peters S. Na Hyun Kim² · Enrique Gomez Gomez · Saiful Miah⁵ · David Eldred Evans Peters S. Na Van Rossum³ · Marieke J. Van Son park Peters S. Na Van Rossum³ · N

Received: 26 August 2020 / Revised: 29 November 2020 / Accepted: 11 December 2020

Propensity matched analysis based on tumour volume and Gleason grade

Comparison between radical prostatectomy and focal therapy (HIFU or cryotherapy)

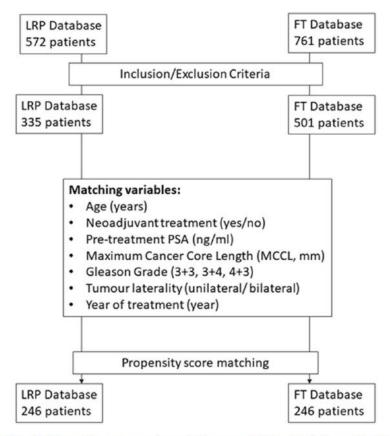


Fig. 1 Flow diagram and matching variables used for cohort development for the primary outcome. After applying the inclusion and exclusion criteria and 1–1 matching, 246 patients remained in each cohort (Radical Prostatectomy (LRP) and Focal Therapy (FT)).

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- Failure defined as need for local salvage treatment (RP or RT) or systemic treatment or development of metastatic disease
 - Biochemical recurrence after RP was not included (24.3% after matching, with 15.9% having salvage RT)
 - Prescence of positive biopsy after FT not included (23.9% after matching)
 - 6.5% had radical after focal
 - 17.1% had 2nd focal (And <3% then had radical treatment)
 - 1.6% had 3 focal treatments)
- One additional focal treatment was allowed

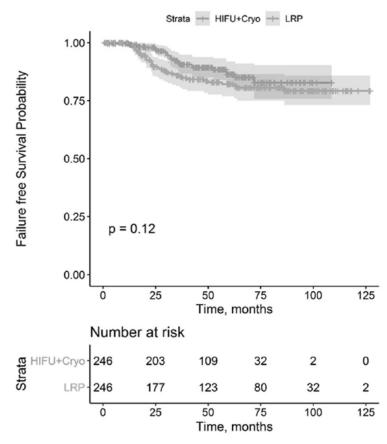


Fig. 2 Primary outcome (definition 1): Kaplan–Meier curve reporting failure free survival against time for laparoscopic radical prostatectomy and focal therapy, after 1–1 matching and single imputation. Failure-free survival (95% CI) in the radical prostatectomy (LRP) compared to focal therapy (HIFU+Cryo) groups was 86% (81–91%) vs. 91% (87–95%) at 3 years, 82% (77–88%) vs. 86% (81–92%) at 5 years and 79% (73–86%) vs 83% (76–90%) at 5 years, respectively (adjusted log rank p value 0.12).

3 year failure free survival

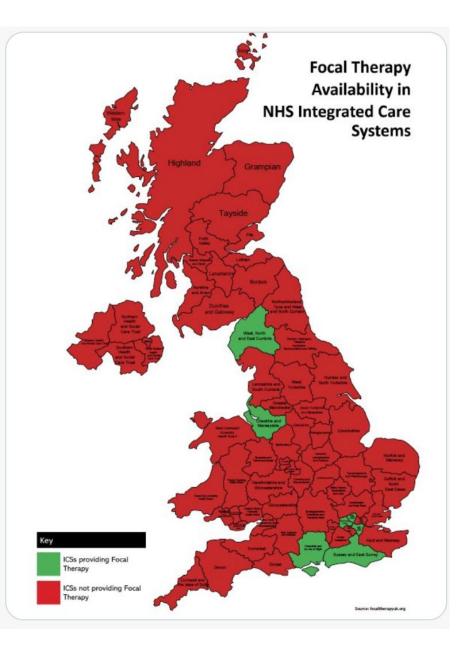
- 86% RP
- 91% FT

5 year failure free survival

- 82% RP
- 86% FT

8 year failure free survival

- 79% RP
- 83% FT



The next challenge is to make it available more widely



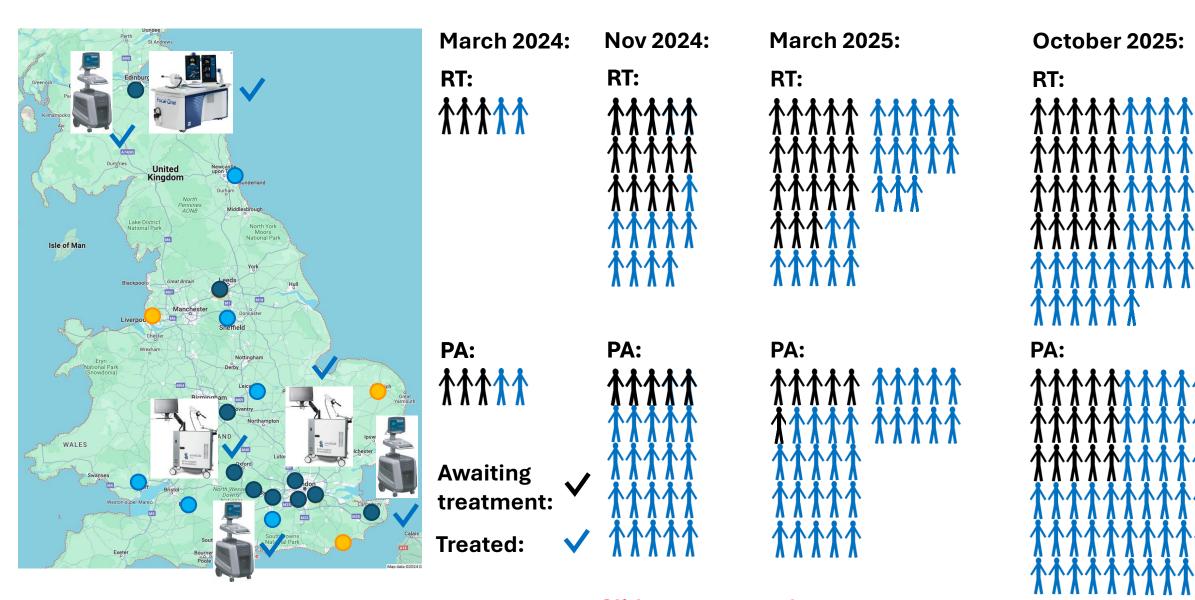
High-Intensity Focused Ultrasound (HIFU) is now available at the Royal United Hospital in Bath (Image: Prost8)

NEWS POLITICS FOOTBALL CELEBS TV CHOICE ROYALS

A breakthrough prostate cancer treatment is being rolled out nationwide on the NHS

High-Intensity Focused Ultrasound (HIFU) has so far only been available at specialist treatment centres in London - but will soon be a treatment option around the country

PART Trial progress since 2023:



Slides courtesy of R Bryant 05/11/25

FOCAL THERAPY SITES **ESTABLISHED + INTERESTED**

Scotland (4)

Western General Hospital, Edinburgh (research) Aberdeen NHS Hospital Glasgow NHS Trust NHS Fife

North West (5)

Wirral University Teaching Hospital NHSFT (Arrowe Park Hospital)

Royal Liverpool University Hospital Aintree Hospital, Liverpool Stepping Hill, Manchester St Helens NHS Trust

Midlands (6)

Queen Elizabeth Hospital, Birmingham Northampton General Hospital NHS Trust Worcestershire Acute Hospital NHS Trust Royal Wolverhampton NHS Trust Russells Hall Hospital, Dudley University Hospitals Coventry and Warwickshire

Wales (1)

Wrexham Maelor Hospital

South West (4)

Royal Bath Teaching Hospitals NHS Trust

University Hospitals Plymouth NHS Trust (Derriford Hospital) Portsmouth University Hospitals University Hospitals Of Dorset NHS Foundation Trust



North East & Cumbria (3)

South Tyneside and Sunderland NHS Foundation Trust (Sunderland Royal Hospital)

Newcastle upon Tyne Hospitals NHS Foundation Trust North Lincolnshire & Goole NHS Trust

Yorkshire & Humber (3)

Airedale NHS Foundation Trust St James Hospital, Leeds (research) Sheffield Teaching Hospitals NHS Foundation Trust (research)

East of England (3)

Norfolk and Norwich University Hospital Colchester & Ipswich Hospital

London (9)

Imperial College Healthcare NHS Trust

University College London Hospitals NHS Foundation Trust

Princess Royal University Hospital (Kings College Hospital NHST)

Milton Keynes University Hospital

King George Hospital, Ilford

Frimley Health Foundation Trust

Royal Berkshire NHS Foundation Trust

Watford General Hospital (West Hertfordshire Teaching Hospitals NHST)

Royal Surrey County Hospital

South East (5)

University Hospital Southampton NHS Foundation Trust

Oxford University Hospitals (research)

Hampshire Hospitals NHS Foundation Trust (Basingstoke Hospital)

Canterbury Hospital

St Mary Hospital, Isle of Wight

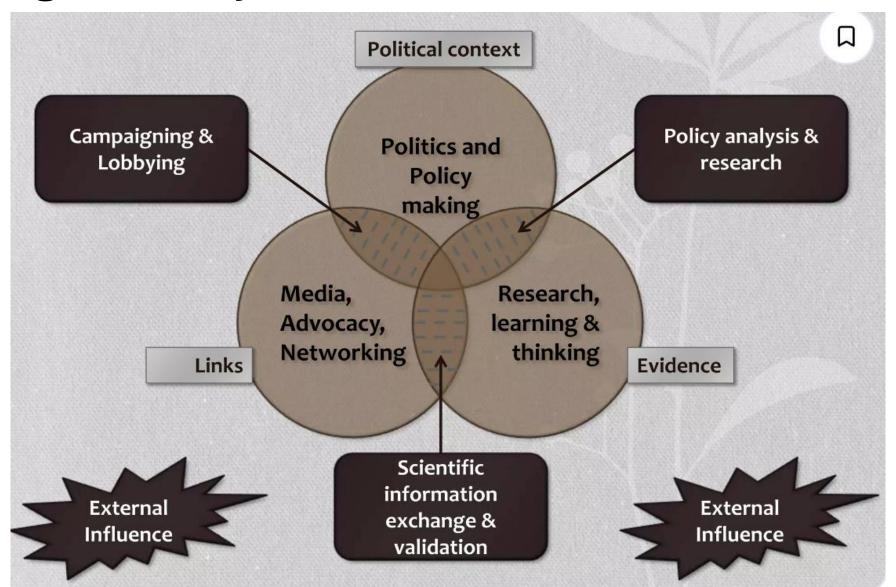








Change is not just about data and evidence



Focal therapy – has it reached prime time?

 The functional outcomes of focal therapy are well described and understood



 The medium term (5-10 year outcomes) of focal therapy are well described and understood



 Patients with unilateral clinically significant disease are offered focal therapy



Every eligible patient can choose focal therapy



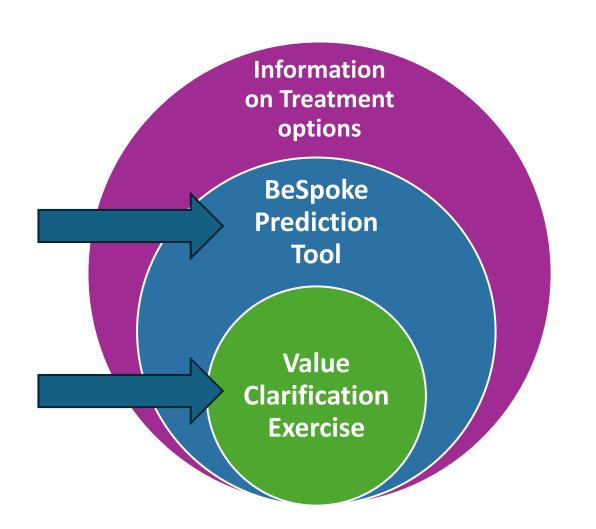
Decisions re active treatment and treatment type are made based on cancer risk and personal choice





How does a patient with localized prostate cancer decide between very different choices?

BeSpoke Decision Support Tool



Personalised decision support based on UK data

- National Prostate Cancer audit for survival and retreatment
- TrueNTH UK Post surgery for functional outcomes
- UCLH active surveillance for MRIled active surveillance outcomes

How likely am I to die from prostate cancer in the next 5 years?

Your clinical parameters:

- Age: 65 years

PSA: 8 ng/mL

Gleason Score: 3+4

- T Stage: T2



Legend:



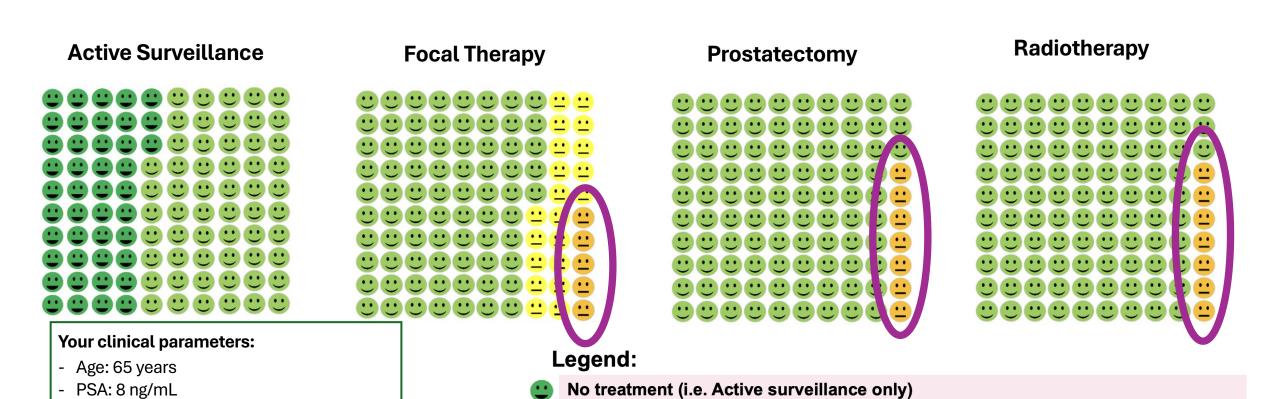
Based on the information you have entered, 96 out of 100 men are alive at 5 years after diagnosis.

Of the men who would not survive, four would die due to causes not related to prostate cancer.

10 times more likely to die of other causes than prostate cancer in 15 years

Will I need further treatment in the next 5 years?

1 in 20 men having focal treatment need radical treatment 1 in 14 men having surgery or radiotherapy need salvage treatment



Second Focal treatment

First treatment only (i.e. focal therapy, Prostatectomy, Radiotherapy)

Progressed to different treatment (i.e. Radiotherapy or surgery after focal therapy;

Salvage radiotherapy after surgery; Hormone treatment after radiotherapy)

Prostate volume: 60 mL

MRI visibility: Visible (Score 4-5)

- Maximal Cancer Core Length: 8mm

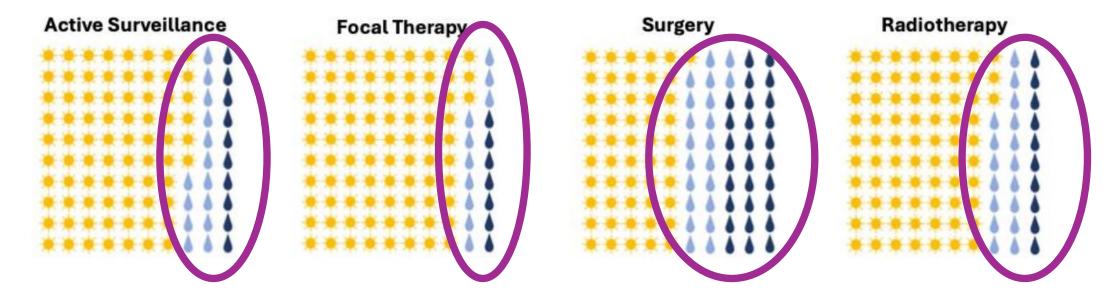
Gleason Score: 3+4

- T Stage: T2

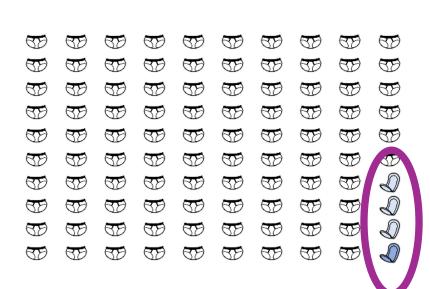
How likely am I to leak urine at 1 year after treatment?

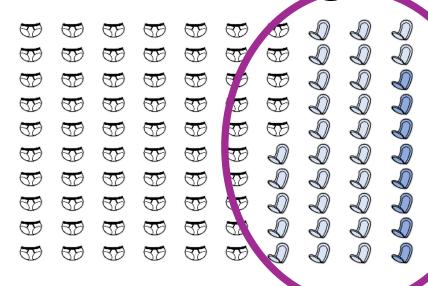
Leaking urine is a common side effect after most prostate cancer treatments. Each treatment carries a different risk. For 100 men with similar urinary function as you (see box), the following icon chart represents the risk of leaking urine at 1 year from receiving each of the following treatments.





Will I need pads for urine leakage at 1 year?







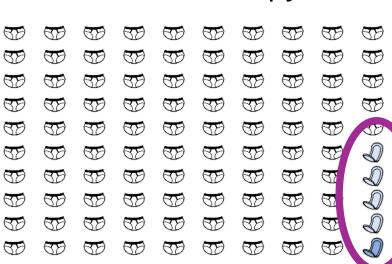
Active
Surveillance

Focal treatment

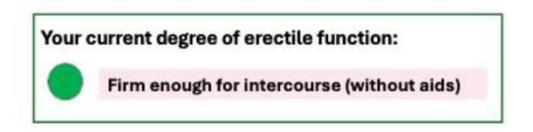
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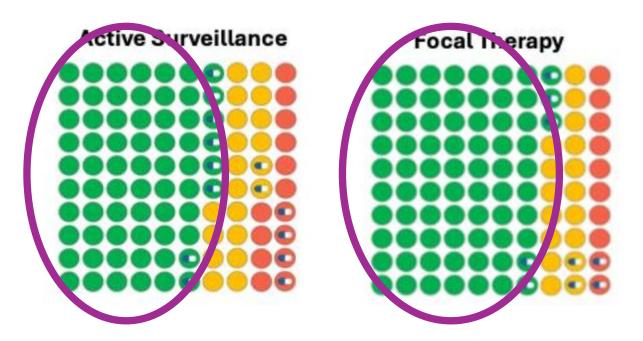
Surgery

Radiotherapy



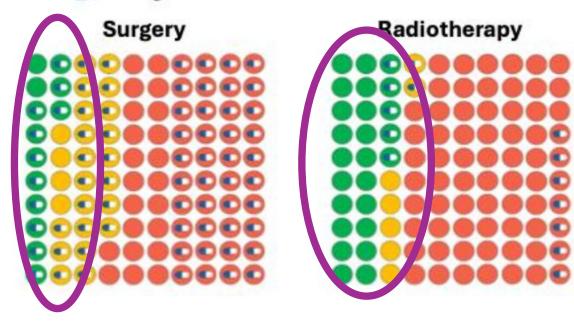
How will my erections be at 12 months after treatment?



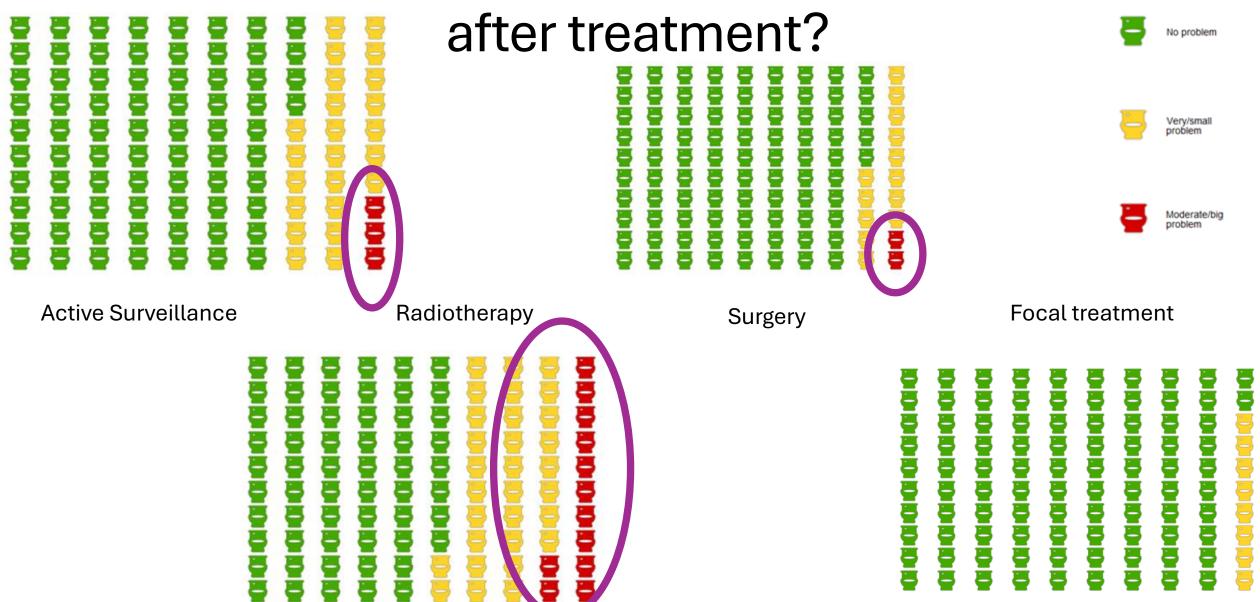


Erectile Function - Legend

- Firm enough for intercourse
- Firm enough for masturbation only
- Not firm enough for any sexual activity or none at all
- Using sexual medication or device



How will my bowel function be at 12 months after treatment?



PSA after radical treatment for prostate cancer

- NPCA data
 - Around 1 in 3 men with a new diagnosis have radiotherapy
 - Around 1 in 6 men with a new diagnosis have surgery to remove the prostate
- PSA is an excellent tool for follow up when the whole prostate has been treated
 - Simple
 - Any detectable PSA needs monitoring

PSA in practice summary

- The first available test for prostate cancer
- PSA based screening leads to a reduction in prostate cancer death
- TRANSFORM will look at new ways to screen
 - MRI
 - Polygenic risk score
- In MRI-led active surveillance PSA density is more helpful than PSA
- PSA is useful in follow up, particularly after radical treatment

Any questions?

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