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No disclosures

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Radioterapia e Oncologia clinica

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THE **E L D E R L Y** - THE **N U M B E R S**

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Life expectancy at 65 years, 2021

eurostat
Statistics Explained

Males

Life expectancy at 65 years, 2021

Legend
- ≥ 78.7 to 79.63
- ≥ 79.63 to 80.27
- ≥ 80.27 to 80.6
- ≥ 80.6 to 81.07
- ≥ 81.07 to 81.27
- ≥ 81.27 to 81.8
- Data not available

Administrative boundaries: © EuroGeographics © UN–FAO © Turkstat
Cartography: Eurostat – IMAGE, 03/2023

EU = 19.3 years
- ≥ 21.0
- 20.0 – < 21.0
- 19.0 – < 20.0
- 18.0 – < 19.0
- 17.0 – < 18.0
- < 17.0
- Data not available

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Popolazione di 80 anni e più
(come % della popolazione totale)
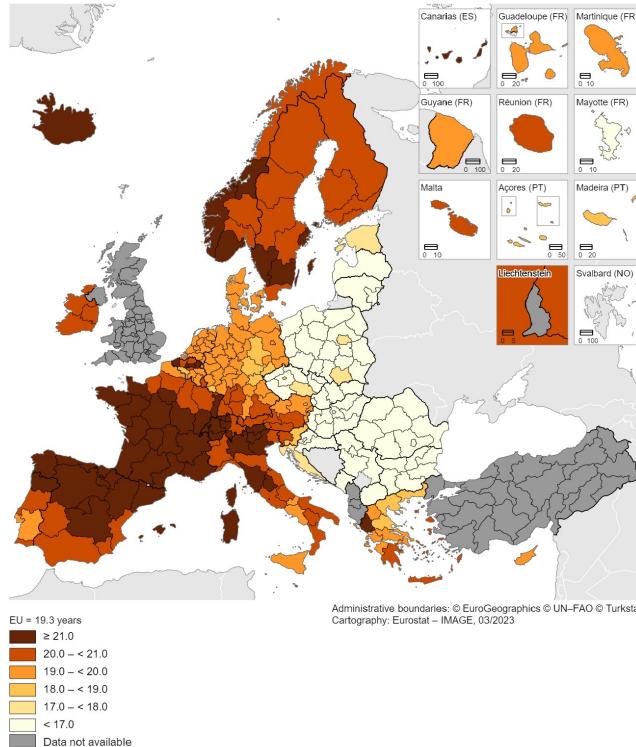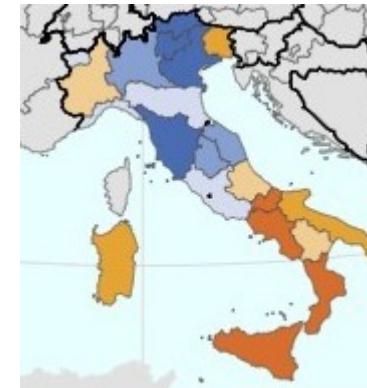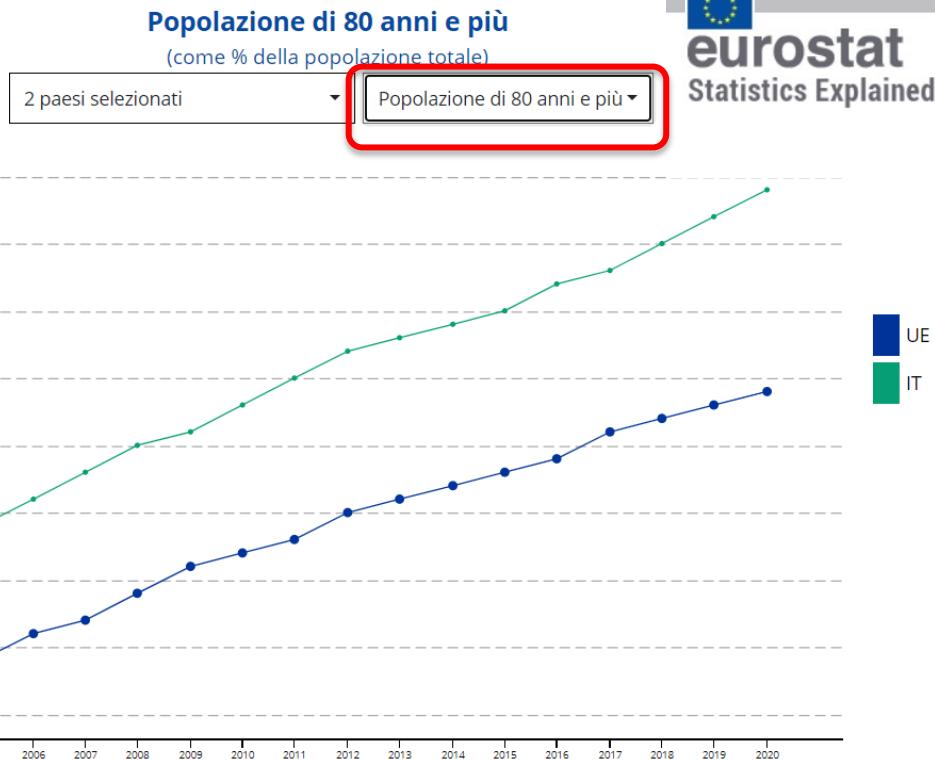
65 y ≤ age ≤ 79 y

- Europ. Union 14.5%
- Italy 15.8%

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European Commission

ECIS - European Cancer Information System

**ESTIMATED DISTRIBUTION OF NEW CASES
OF PROSTATE CANCER IN 2020– BY AGE GROUP**

0-19	20-44	45-69	70+
4 cases	292 cases	165 164 cases	170 054 cases

A **All Stages**
Age 10-84

AYA
[Adolescents Young Adults]

Incidence per 100,000

Age at Diagnosis (Years)
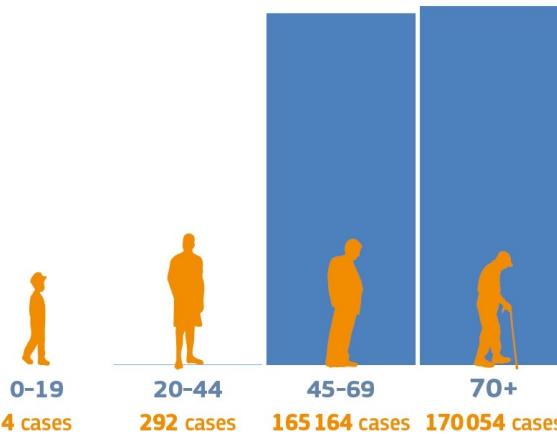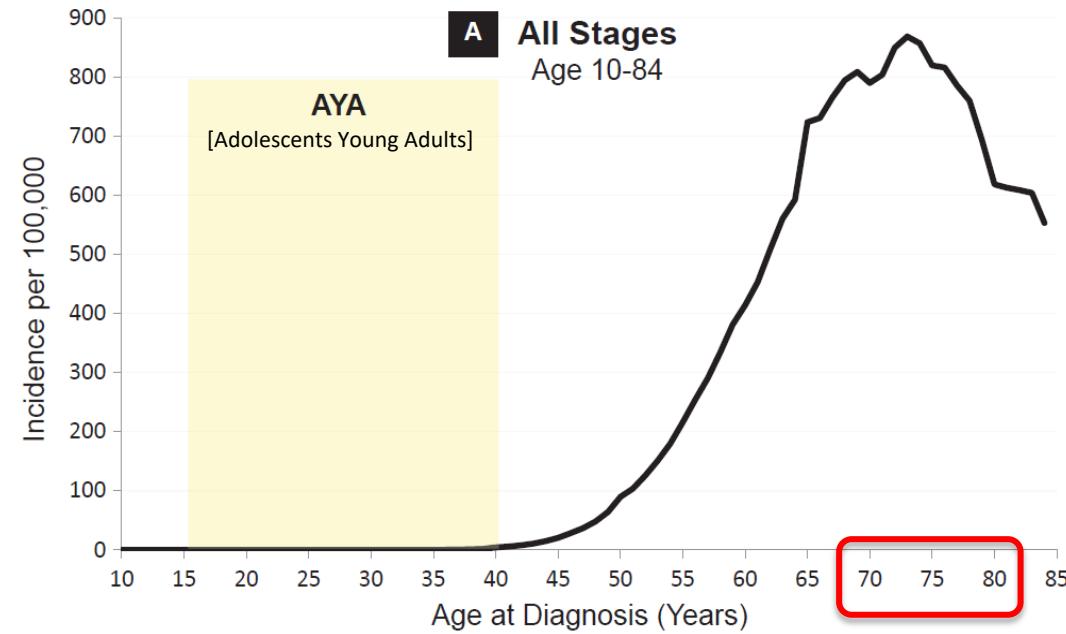
Bleyer A, et al. Cancer 2020

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TABLE 10   Five leading causes of cancer death in the United States by age and sex, 2020

Ranking	All ages	Birth to 19 years	Aged 20–39 years	Aged 40–49 years	Aged 50–64 years	Aged 65–79 years	Aged 80 years and older
Male							
All sites	317,731	932	3851	8655	70,248	144,420	89,624
1	Lung & bronchus	Brain & ONS	Colon & rectum	Colon & rectum	Lung & bronchus	Lung & bronchus	Lung & bronchus
	72,949	282	562	1574	16,517	37,860	17,329
2	Prostate	Leukemia	Brain & ONS	Lung & bronchus	Colon & rectum	Prostate	Prostate
	32,707	218	541	1059	7860	13,407	15,995
3	Colon & rectum	Bones & joints	Leukemia	Brain & ONS	Pancreas	Pancreas	Colon & rectum
	28,043	107	433	813	6024	12,080	7159
4	Pancreas	Soft tissue (including heart)	Testis	Pancreas	Liver[a]	Colon & rectum	Urinary bladder
	24,279	88	212	696	5650	10,884	5751
5	Liver[a]	Liver[a]	Non-Hodgkin lymphoma	Esophagus	Esophagus	Liver[a]	Pancreas
	18,636	27	198	405	3614	9298	5369

Siegel RL, et al. Cancer Statistics 2023

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European Commission

ECIS - European Cancer Information System

PCa incidence in the EU elderly (75-85 yrs): 0.5% - 0.7%

ESTIMATED DISTRIBUTION OF NEW CASES OF PROSTATE CANCER IN 2020 – BY AGE GROUP

0-19	20-44	45-69	70+
4 cases	292 cases	165 164 cases	170 054 cases
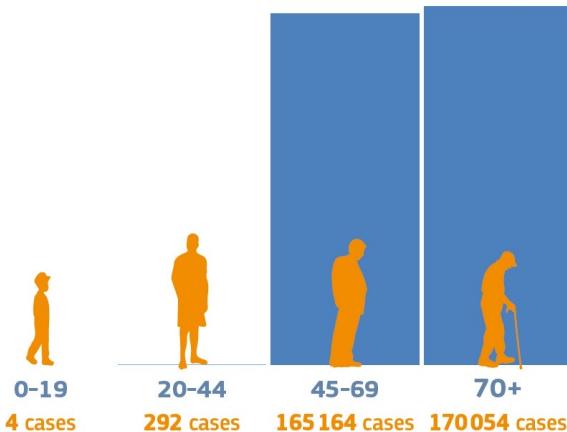
Estimated incidence by country

EU27, Male, Prostate, 75 to 85 years, 2022

- 459.7 – 568.4
- 568.4 – 677.0
- 677.0 – 785.7
- 785.7 – 894.3
- 894.3 – 1 003.0

Age standardised rate (European 2013) per 100.000

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European Commission

ECIS - European Cancer Information System

PCa mortality in the EU elderly (75-85 yrs): 0.3% - 0.4%
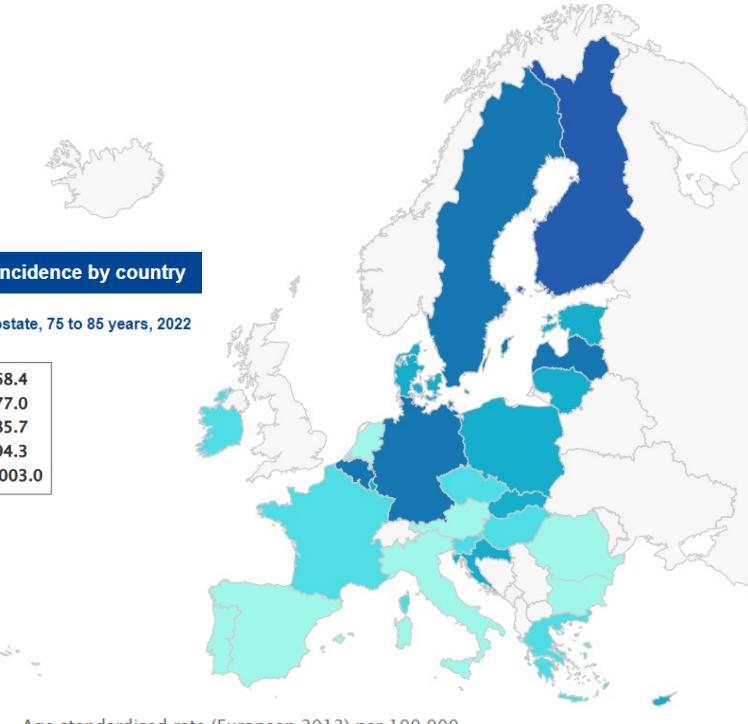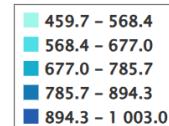
[75 - 85 yrs]

- 100.000 new PCa pts per year

- 60.000 PCa pts die per year

Estimated mortality by country - summary

Male, Prostate, 75 to 85 years, 2022

Country ▲	Number of cases ⬍
Italy	6520
EU-27	55772

Estimated mortality by country

EU27, Male, Prostate, 75 to 85 years, 2022

	227.3 – 315.1
	315.1 – 402.8
	402.8 – 490.6
	490.6 – 578.3
	578.3 – 666.1

Age standardised rate (European 2013) per 100.000

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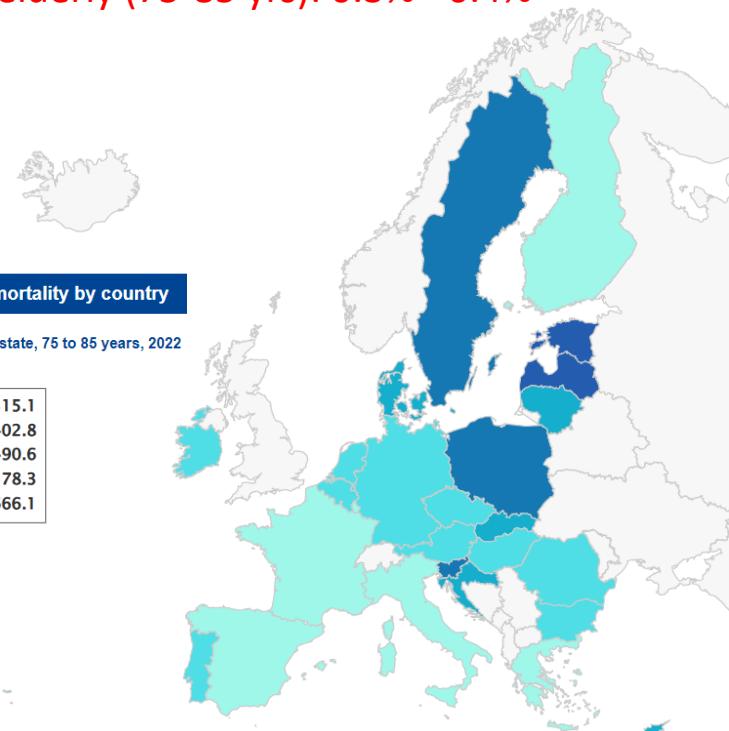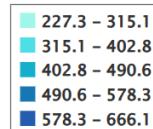
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Age

- Between 65 and 79 y - 14.5%
- More than 80 y - 6%

PCa (75-85 yrs)

- incidence: 0.5% - 0.7% - 100.000/year
- mortality: 0.3% - 0.4% - 60.000/year
- second cause of cancer death in the elderly

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THE **E L D E R L Y** - THE **S C R E E N I N G**

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International Society of Geriatric Oncology (SIOG)

17 screening tools in elderly cancer pts

Decoster L, et al. Ann of Oncol 2015

1. G8
2. Vulnerable Elders Survey-13
3. Flemish version of the Triage Risk Screening Tool
4. Groningen Frailty Indicator
5. Study of Osteoporotic Fractures Index
6. KPS
7. ECOG
8. Physical Frailty Phenotype
9. Barber Questionnaire
10. Identification of Seniors at Risk
11. Oncogeriatric Screen
12. Abbreviated Comprehensive Geriatric Assessment
13. Senior Adult Oncology Program 2 screening
14. Physical Performance Test
15. Handgrip Test
16. Time up and go
17. Gerhematolim

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EAU/ESTRO/

SIOG

G8 screening tool.

A. Has food intake declined over the past 3 mo due to loss of appetite, digestive problems, chewing, or swallowing difficulties?	Severe decrease in food intake	0
	Moderate decrease in food intake	1
	No decrease in food intake	2
B. Weight loss during the last 3 mo?	Weight loss >3 kg	0
	Does not know	1
	Weight loss 1–3 kg	2
	No weight loss	3
C. Mobility	Bed- or chair-bound	0
	Able to get out of bed/chair but does not go out	1
	Goes out	2
D. Neuropsychological problems?	Severe depression or dementia	0
	Mild dementia	1
	No psychological problems	2
E. Body mass index (BMI)?	BMI <19 kg/m^2	0
	BMI 19 to <21 kg/m^2	1
	BMI 21 to <23 kg/m^2	2
	BMI ≥23 kg/m^2	3
F. Takes more than 3 prescription drugs per day?	Yes	0
	No	1
G. In comparison to other people of the same age, how does the patient consider his health status?	Not as good	0
	Does not know	0.5
	As good	1
	Better	2
H. Age	≥86 yr	0
	80–85 yr	1
	<80 yr	2

Droz JP, et al. Eur Urol 2017

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SIOG

The Mini-COG™ screening tool.

Step 1: Three words registration

Look directly at person and say, "Please listen carefully. I am going to say three words that I want you to repeat back to me now and try to remember. The words are [select a list of words from the versions below]. Please say them for me now." If the person is unable to repeat the words after three attempts, move on to Step 2 (clock drawing).

The following and other word lists have been used in one or more clinical studies. For repeated administrations, use of an alternative word list is recommended.

Version 1	Version 2	Version 3	Version 4	Version 5	Version 6
Banana	Leader	Village	River	Captain	Daughter
Sunrise	Season	Kitchen	Nation	Garden	Heaven
Chair	Table	Baby	Finger	Picture	Mountain

Step 2: Clock drawing

Say: "Next, I want you to draw a clock for me. First, put in all of the numbers where they go." When that is completed, say: "Now, set the hands to 10 past 11." Use a preprinted circle for this exercise. Repeat the instructions as needed, as this is not a memory test. Move to Step 3 if the clock is not complete within 3 min.

Step 3: Three words recall

Ask the person to recall the three words you stated in Step 1. Say: "What were the three words I asked you to remember?" Record the word list version number and the person's answers.

Droz JP, et al. Eur Urol 2017

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Cumulative Illness Rating Scale - Geriatrics (CIRS-G)

| 1	Cardiac (heart only)
2	Hypertension (rating is based on severity; affected systems are rated separately)
3	Vascular (blood, blood vessels and cells, marrow, spleen, lymphatics)
4	Respiratory (lungs, bronchi, trachea below the larynx)
5	ENT (eye, ear, nose, throat, larynx)
6	Upper GI (esophagus, stomach, duodenum. Biliar and parcreatic trees; do not include diabetes)
7	Lower GI (intestines, hernias)
8	Hepatic (liver only)
9	Renal (kidneys only)
10	Other GU (ureters, bladder, urethra, prostate, genitals)
11	Musculo-Skeletal-Integumentary (muscles, bone, skin)
12	Neurological (brain, spinal cord, nerves; do not include dementia)
13	Endocrine-Metabolic (includes diabetes, diffuse infections, infections, toxicity)
14	Psychiatric/Behavioural (includes dementia, depression, anxiety, agitation, psychosis)
	All body systems are scores on a 0 - 4 scale. - 0: No problem affecting that system. - 1: Current mild problem or past significant problem. - 2: Moderate disability or morbidity and/or requires first line therapy. - 3: Severe problem and/or constant and significant disability and/or hard to control chronic problems. - 4: Extremely severe problem and/or immediate treatment required and/or organ failure and/or severe functional impairment.
Total score 0-56	

Droz JP, et al. Eur Urol 2017

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Summary of the different steps in health status evaluation and estimated time required

Step	Tools	Time	Who can do it?
Mandatory initial step	G8	5 min	Trained nurse
	Mini-COG™	5 min	Trained nurse
Simplified geriatric evaluation if G8 score is ≤14	ADL	1 min	Trained nurse
	CIRS-G	15 min	Trained nurse and/or doctor
	Weight loss	1 min	Trained nurse
Comprehensive geriatric assessment if geriatric intervention needed	Screening tools and complete clinical examination	2 h to 1 d in hospital	Geriatrician + other health professionals

Droz JP, et al. Eur Urol 2017

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Radioterapia Oncologica:
l'evoluzione al servizio dei pazienti

EAU-EANM-ESTRO-ESUR-ISUP-SIOG
2023 Guidelines

PROSTATE CANCER - LIMITED UPDATE MARCH 2023

Screening by G8 and mini-COG™

G8 score > 14/17
no geriatric
evaluation is
needed

G8 score ≤ 14/17
a full geriatric evaluation is
mandatory

- Abnormal ADL: 1 or 2
- Weight loss 5-10%
- Comorbidities CISR-G grades 1-2

- Abnormal ADL: > 2
- Weight loss > 10%
- Comorbidities CISR-G grades 3-4

Geriatric assessment
then geriatric intervention

Group 1
Fit

Group 2
Vulnerable

Group 3
Frail

Revers. impairment

Irrevers. impairment

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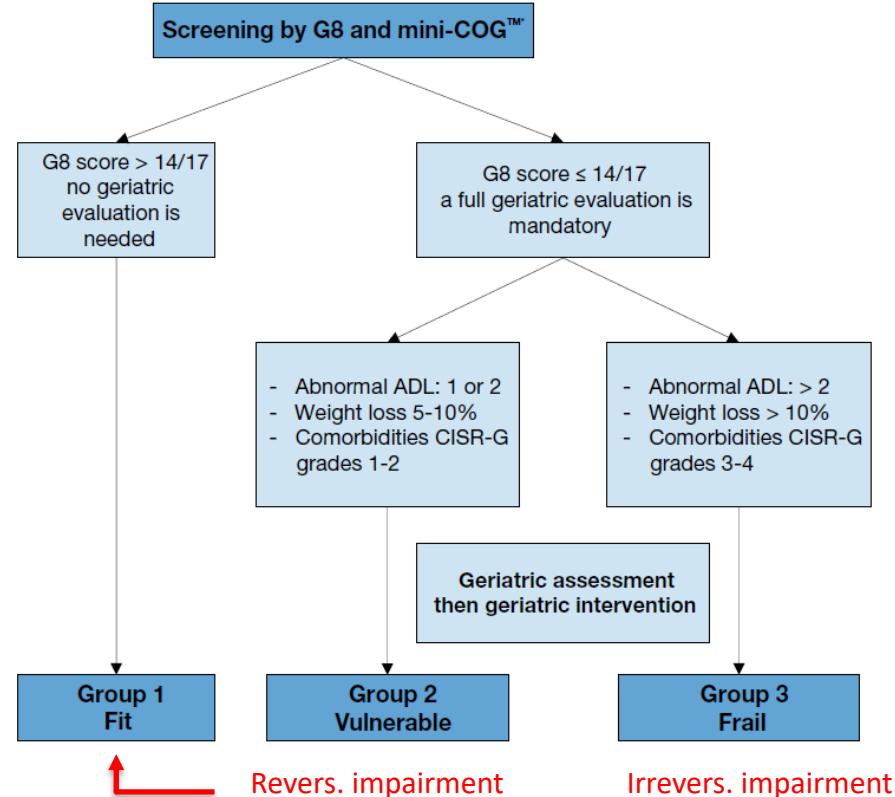
EAU-EANM-ESTRO-ESUR-ISUP-SIOG 2023 Guidelines

PROSTATE CANCER - LIMITED UPDATE MARCH 2023

Group 1 Fit

Group 2 Vulnerable

Screening by G8 and mini-COG™

G8 score > 14/17 no geriatric evaluation is needed

G8 score ≤ 14/17 a full geriatric evaluation is mandatory

- Abnormal ADL: 1 or 2
- Weight loss 5-10%
- Comorbidities CISR-G grades 1-2

- Abnormal ADL: > 2
- Weight loss > 10%
- Comorbidities CISR-G grades 3-4

Geriatric assessment then geriatric intervention

Group 1 Fit

Group 2 Vulnerable

Group 3 Frail

Revers. impairment

Irrevers. impairment

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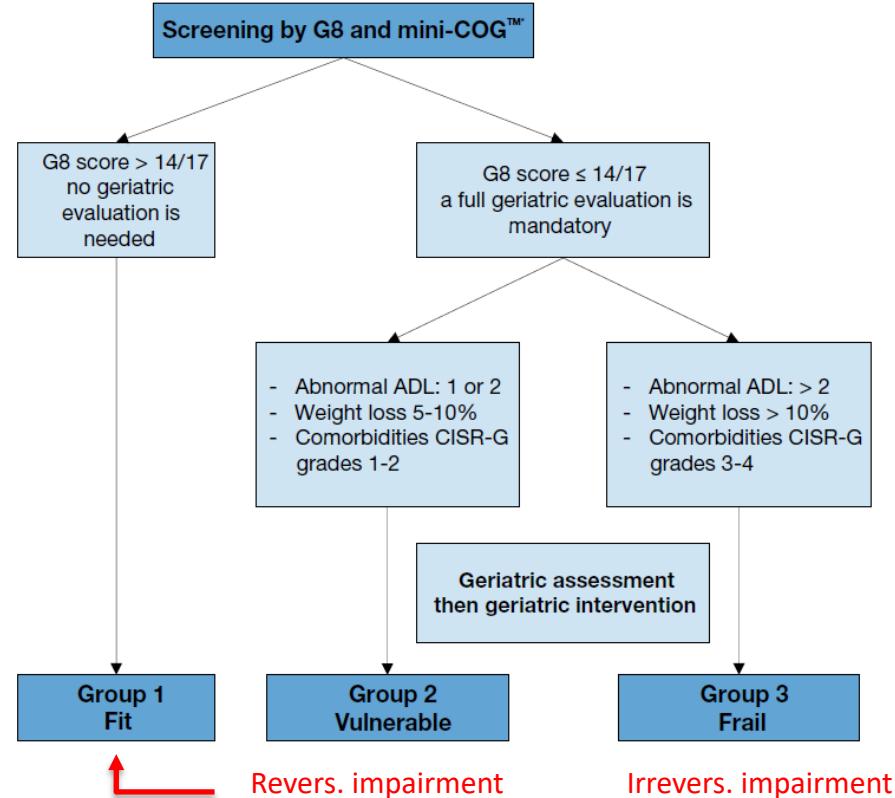
THE **E L D E R L Y** - THE **S C R E E N I N G**

- Do not rely only on the age

- Use screening tools

- Ask for geriatric assessment and intervention in vulnerable pts
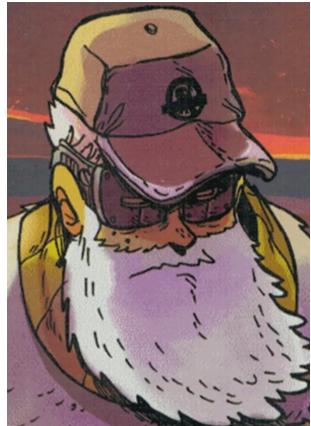
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THE **E L D E R L Y - ** THE ** T R E A T M E N T**

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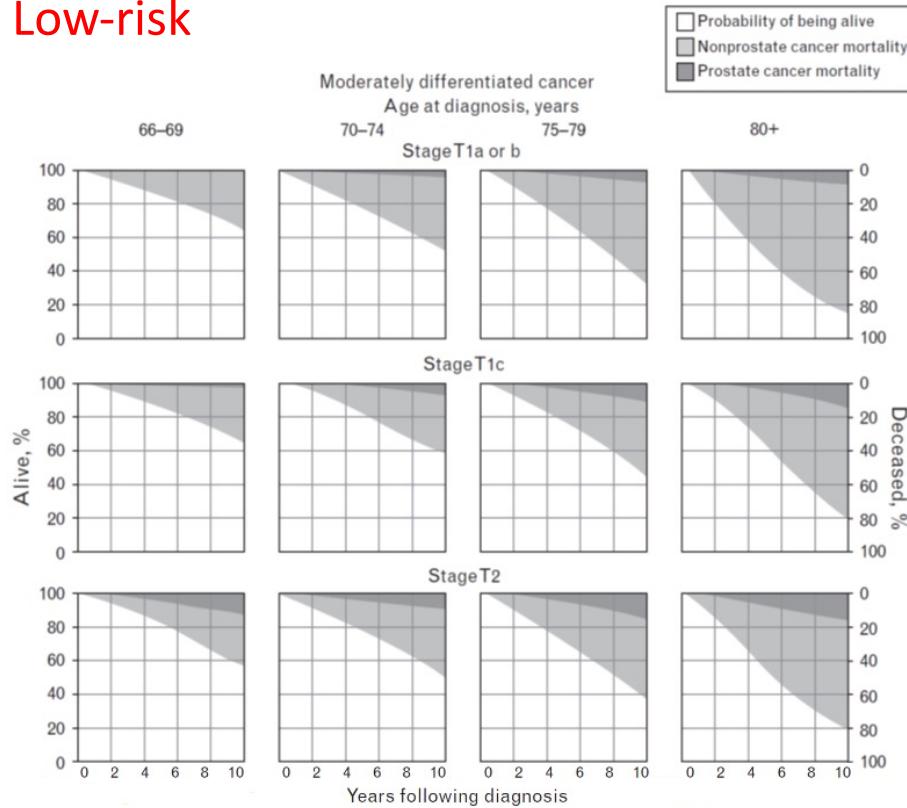
Low-risk


[1992-2009] PCa patients managed with non-curative intent

Lu-Yao G, et al. JAMA 2009

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Low-risk vs high-risk
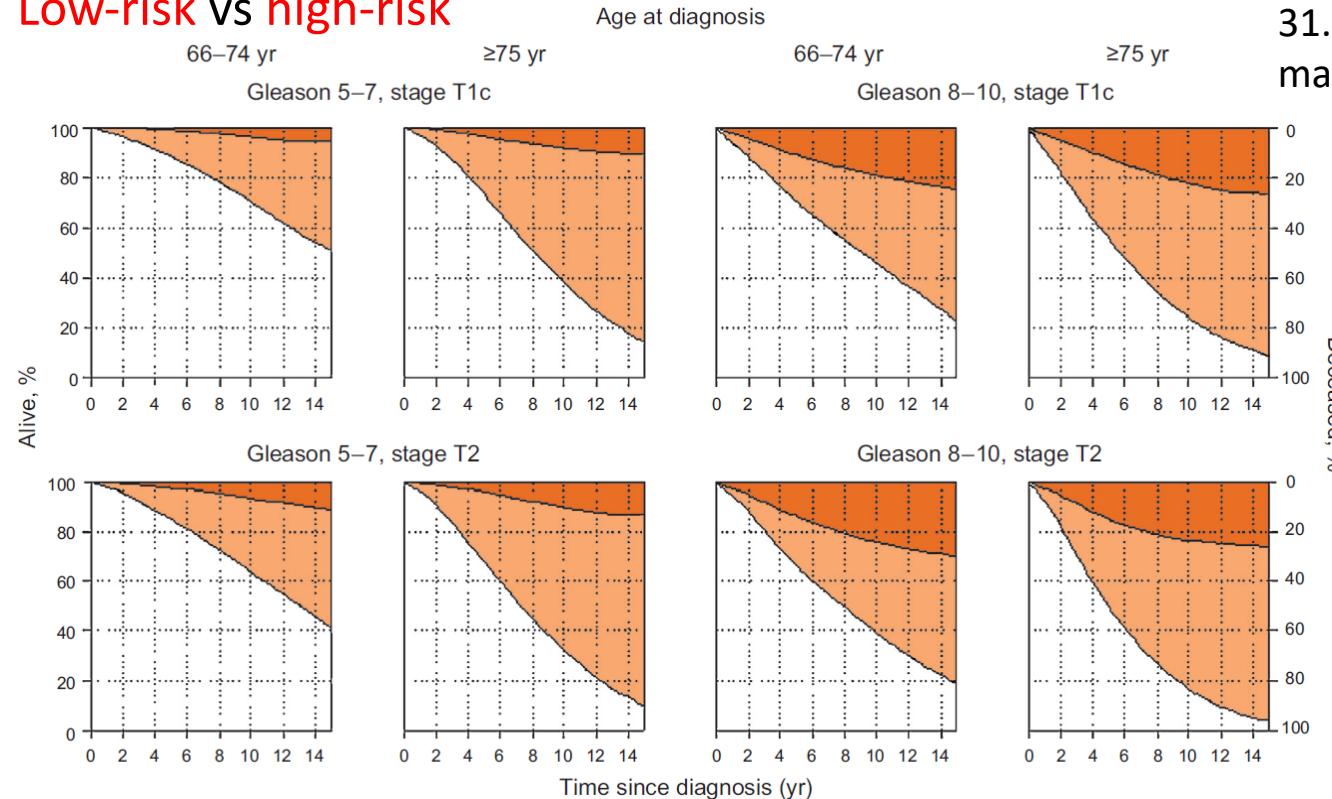
31.137 localized PCa patients
managed with non-curative intent

Age at diagnosis

Lu-Yao GL, et al. Eur Urol 2015

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High-risk

12.184 high-risk PCa patients [T3-4, or T1-2, 50 ≤ PSA ≤ 99 ng/ml] managed with non-curative intent
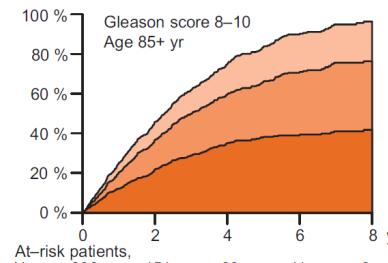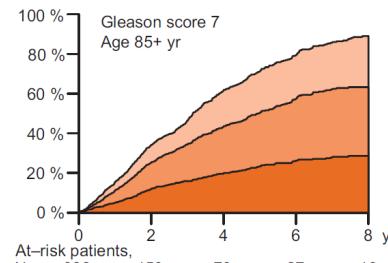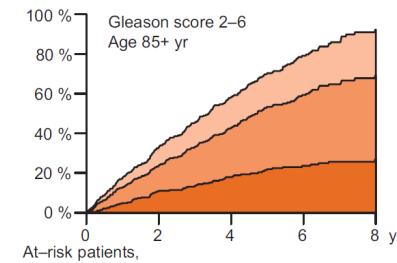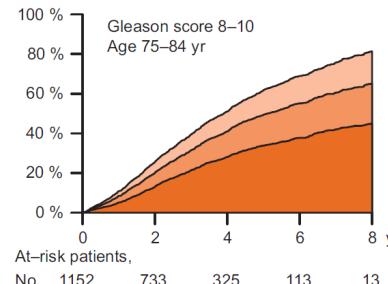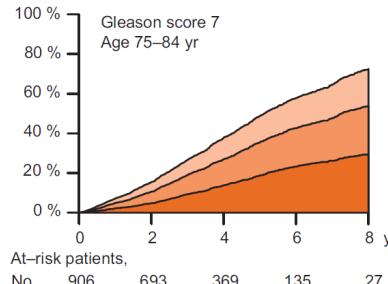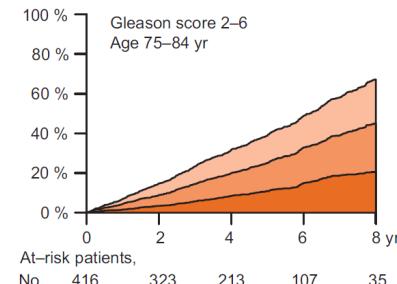
Age > 85, 8-yrs PCSM: 42% (95%CI, 37-47%)

Akre O, et al. Eur Urol 2011

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Radioterapia Oncologica:
l'evoluzione al servizio dei pazienti

High-risk

19.190 high-risk nonmetastatic PCa pts treated with RP or RT

	Men with prostate cancer (n)	Men with prostate cancer receiving RP or RT, % (95% CI)	10-yr survival of men without prostate cancer, % (95% CI)
Age <65 yr			
CCI 0	3817	82 (80–83)	91 (91–91)
CCI 1	389	76 (71–80)	79 (79–80)
CCI 2	191	72 (65–78)	68 (67–70)
CCI ≥3	86	52 (41–63)	46 (43–48)
Age 65–69 yr			
CCI 0	3322	70 (69–72)	82 (82–82)
CCI 1	552	57 (53–61)	66 (66–67)
CCI 2	255	61 (54–67)	59 (56–60)
CCI ≥3	133	41 (32–49)	36 (33–38)
Age 70–74 yr			
CCI 0	3547	44 (43–46)	70 (70–70)
CCI 1	736	36 (32–39)	52 (51–53)
CCI 2	437	28 (24–33)	42 (41–44)
CCI ≥3	237	23 (18–29)	24 (23–25)
Age 75–79 yr			
CCI 0	3575	10 (9–11)	52 (51–52)
CCI 1	1000	6 (5–8)	33 (32–34)
CCI 2	521	3 (4–9)	28 (27–29)
CCI ≥3	392	5 (3–8)	15 (14–16)

Bratt O et al, Eur Urol 2015

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Low-risk
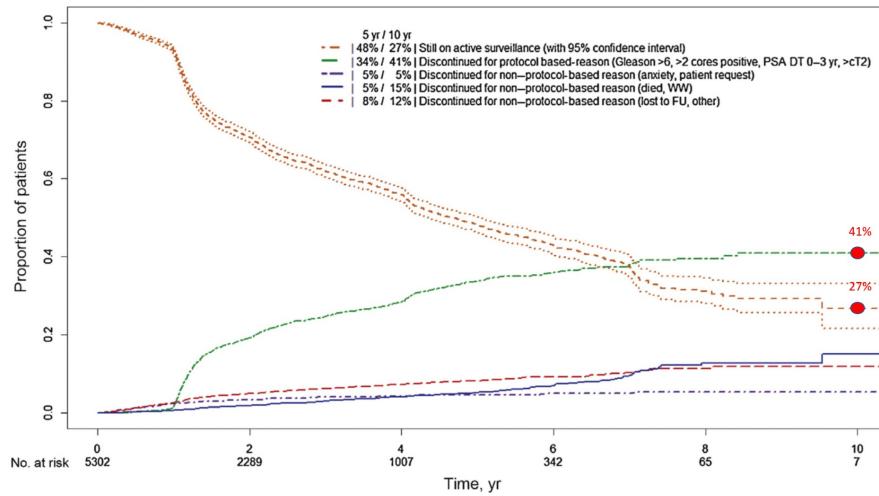
PRIAS - [Bokhorst LP et al, Eur Urol 2016]

[Cooperberg MR et al, JAMA 2020]

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High-risk

	N	Positive True/False	Negative True/False	AUC (95% CI)
Primary analysis				
Any metastatic disease	150	18/9	94/29	
	145	34/2	103/6	
Pelvic nodal	150	9/4	106/31	
	145	29/1	109/6	
Distant metasases	150	13/9	117/11	
	145	22/1	120/2	
Sensitivity analysis: equivocal lesions treated as positive				
Any metastatic disease	150	26/35	68/21	
	145	35/11	94/5	
Pelvic nodal	150	11/11	99/29	
	145	29/2	108/6	
Distant metasases	150	16/37	89/8	
	145	22/11	110/2	

■ Conventional imaging ■ PSMA PET-CT

Hofman MS et al, Lancet 2020

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High-risk

PSMA PET-CT   CT

Hofman MS et al, Lancet 2020

	Patients (n)	High/ medium	Low/ potentially ignored		Rate (95% CI)	p value
Management effect						
First-line diagnostic imaging	152	23	129		15% (10–22%)	0·0076
	147	41	106		28% (21–36%)	
Second-line diagnostic imaging	135	7	128		5% (2–10%)	..
	146	39	107		27% (20–35%)	

% (95% CI)

Recommendations	Strength rating
When using PSMA-PET or whole body MRI to increase sensitivity, be aware of the lack of outcome data of subsequent treatment changes.	Strong

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National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov

Image-guided Focal Brachytherapy Utilizing Combined 18F-DCFPyl PET/CT	NCT03861676	Radiation: Focal brachyth/PSMA PET
		Drug: (18F)DCFPyL
PSMA-PET/MRI Low- and Intermediate-Risk Prostate Cancer	NCT04243941	Drug: 68Ga-HBED-CC-PSMA
Stereotactic Prostate Radiotherapy With Dose Escalation Focused on the "Dominant Intra-prostatic Lesion" (DIPL) Delineated by Multi-parametric MRI and 68Ga-PSMA PET (Prostate-SIB-PSMA)	NCT05599737	Radiation: Integrated boost
Functional Image-Guided Carbon Ion Irradiation With Simultaneous Integrated Boost for Prostate Cancer	NCT05010343	Radiation: carbon ion irradation
		Radiation: Carbon Ion Irradiation With SIB
Hormone Therapy (Apalutamide) and Image-guided Stereotactic Body Radiation Therapy for the Treatment of Patients With Prostate Cancer, HEATWAVE Trial	NCT06067269	Drug: Apalutamide
24 Gy in One Fraction Urethral-sparing "HDR Like" SBRT for Prostate Cancer	NCT05936736	Radiation: prostate SBRT
Integrated Boost to the Dominant Intraprostatic Nodule Based on Ga-68 PSMA PET/MR Study of SBRT With Prostate Cancer	NCT04599699	Radiation: SBRT
Focal Therapy With Stereotactic Body Radiation Therapy (SBRT) for Patients With a Single Prostate Tumor	NCT05616650	Drug: 18F-DCFPyL / Radiation: SBRT
18F-DCFPyL Imaging as a Method to Assess Treatment Response to Stereotactic Body Radiation Therapy	NCT05155046	Drug: 18F-DCFPyL
Enzalutamide in Androgen Deprivation Therapy With Radiation Therapy for High Risk, Clinically Localised, Prostate Cancer	NCT02446444	Drug: Enzalutamide
Observational Study on Extreme Hypofractionation for Localized Prostate Cancer	NCT05344235	SBRT

Focus Your Search
(all filters optional)   « Hide

Condition or disease ⓘ
Localized Prostate Cancer

Other terms ⓘ
PSMA PET

Intervention/Treatment ⓘ
Radiotherapy

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Prognostic biomarkers

4K (tPSA, fPSA, iPSA, hK2)

$PHI = ([-2]proPSA/fPSA) \times \sqrt{tPSA}$

- 4765 biopsied ProtecT participants
- Aim: detect any grade PCa and high-risk (Gleason ≥ 7)

Model	High-grade prostate cancer	
	Serum AUC (95% CI)	Increment over "Age + total PSA"
Age + total PSA	0.785 (0.745 to 0.824)	
Age + total PSA and free-to-total PSA ratio	0.839 (0.808 to 0.871)	0.055 (P < .001)
Age + panel of four kallikrein markers	0.859 (0.830 to 0.888)	0.075 (P < .001)

Bryant RJ et al, J Natl Cancer Inst 2015
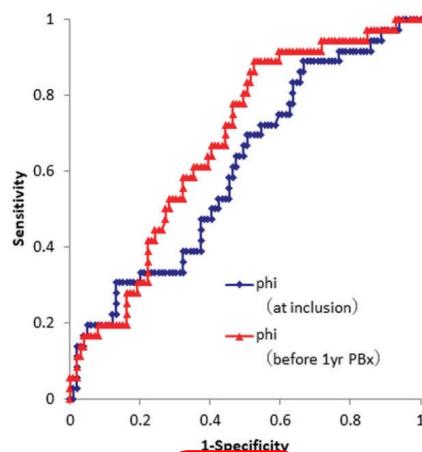
variable	AUC	optimal cutoff point	sensitivity	1-specificity	p value
phi (inclusion)	0.607	29.56	0.67	0.89	refference
phi (before 1yr PBX)	0.679	35.92	0.53	0.89	0.08

Kato T et al, Pros Ca Prost Dis 2021;1-6

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Prognostic biomarkers

- 1211 AS pts (96% GG1, 4% GG2)
- Median FU 3 y
- 289 (23.8%) pts reclassified
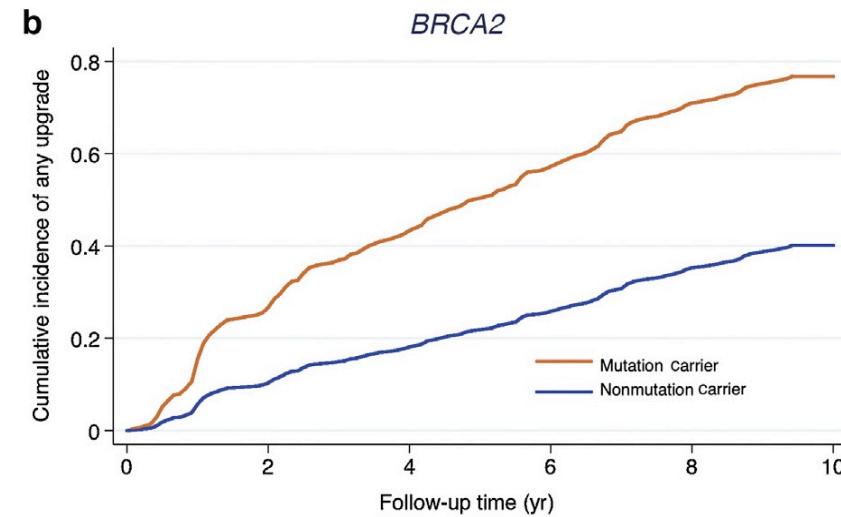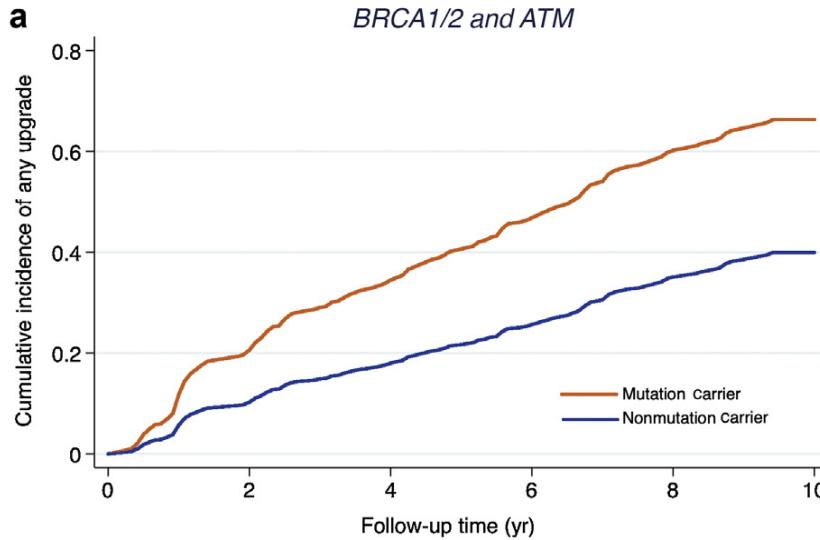
Carter HB et al, Eur Urol 2022

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Prognostic biomarkers

| Test(s)	Company	List Price,* USD	Sample Requirement	Clinical Utility/Intended Use	Comments
Decipher Biopsy and Decipher Postoperative	Decipher Biosciences (formally Genome Dx)	$5,150	FFPE tissue from prostate biopsy, or	Categorize patients into low/high risk to stratify patients to surveillance *v* treatment (and intensity of treatment)	Evaluates mRNA expression levels of 22 genes from FFPE tissue; generates score from 0 to 1.0
			Prostate tissue after RP	Postprostatectomy for patients with adverse pathologic features to guide whether surveillance, adjuvant, or salvage therapy may be warranted	
Onco*type* Dx GPS	Genomic Health	$4,520	Tumor tissue from original biopsy in neutral buffered formalin; prostatectomy specimens not accepted	Biopsy-based likelihood of adverse pathologic features (Grade Group $\geq$ 3 or extracapsular extension); identify those who may benefit from surveillance *v* treatment	GPS ranges from 0 to 100 based on mRNA expression of 17 genes across four pathways
Prolaris Biopsy and Prolaris Postprostatectomy	Myriad Genetic Laboratories	$3,900	FFPE tissue from: prostate tumor biopsy, or prostatectomy specimens	Aggressiveness of cancer; provides a 10-year risk of metastasis after definitive therapy, and disease-specific mortality under conservative management	mRNA expression of cell-cycle progression genes are used to calculate the score; clinical factors are subsequently added for risk assessment
ProMark, Proteomic Prognostic test for prostate cancer	MetaMark	$3,900	Requires tissue collected with patented biopsy kit available from MetaMark	Uses automated image recognition technology to determine the likelihood of Grade Group $\geq$ 2 or stage $\geq$ T3b	Expression of 8 proteins; uses automated image recognition technology to generate a score from 1 to 100 indicating the aggressiveness of prostate cancer

Eggener SE et al, J Clin Oncol 2019

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Use of the Decipher genomic classifier among men with prostate cancer in the United States

JNCI Cancer Spectrum, 2023, **7**(5), pkad052

https://doi.org/10.1093/jncics/pkad052
Advance Access Publication Date: August 1, 2023
Article

	GC biopsy ordered	
	n	Median (Q1, Q3)
Overall	3949	0.50 (0.34, 0.65)
Clinical grade group		
1	1483	0.43 (0.29, 0.56)
2	1464	0.51 (0.35, 0.64)
3	514	0.60 (0.43, 0.74)
4	186	0.66 (0.50, 0.81)
5	160	0.81 (0.62, 0.91)
Clinical stage		
T1	2434	0.48 (0.34, 0.62)
T2	1033	0.53 (0.36, 0.69)
T3a	65	0.57 (0.43, 0.77)
T3b	38	0.83 (0.68, 0.90)
T3 (NOS)	14	0.64 (0.59, 0.72)
T4	13	0.90 (0.69, 0.95)
Percent positive cores		
<50%	2182	0.48 (0.34, 0.62)
≥50%	835	0.57 (0.38, 0.73)
Prostate specific antigen		
PSA < 10	2738	0.48 (0.34, 0.63)
10 ≤ PSA ≤ 20	513	0.57 (0.40, 0.71)
PSA > 20	184	0.59 (0.45, 0.82)
NCCN risk group		
Very low / low	1006	0.42 (0.29, 0.55)
Favorable-intermediate	769	0.49 (0.34, 0.63)
Intermediate (NOS)	158	0.48 (0.35, 0.59)
Unfavorable-intermediate	952	0.56 (0.39, 0.70)
High / very high	465	0.62 (0.47, 0.79)
Pathological grade group		
1	92	0.48 (0.32, 0.62)
2	641	0.53 (0.37, 0.66)
3	236	0.61 (0.48, 0.76)
4	33	0.63 (0.45, 0.77)
5	60	0.75 (0.62, 0.89)
Pathological stage		
T2	727	0.53 (0.38, 0.65)
T3a	232	0.59 (0.43, 0.74)
T3b	94	0.69 (0.54, 0.82)
T3 (NOS)	13	0.75 (0.53, 0.82)
T4	8	0.48 (0.38, 0.64)
De novo metastatic		
No	3644	0.49 (0.34, 0.63)
Yes	42	0.88 (0.68, 0.93)
Lymph node invasion		
No/Unknown	3892	0.49 (0.34, 0.64)
Yes	57	0.84 (0.69, 0.92)

GC biopsy score

Test type
GC biopsy
GC post-op

Count

Ordering year
2013-2014 · 2015 · 2016 · 2017 · 2018-2020

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l'evoluzione al servizio dei pazienti

Platinum Opinion

The State of the Science on Prostate Cancer Biomarkers: The San Francisco Consensus Statement

EUROPEAN UROLOGY 76 (2019) 268–272

eau
European Association of Urology

Molecular Biomarkers in Localized Prostate Cancer: ASCO Guideline

Journal of Clinical Oncology®

ASCO
1474 Volume 38, Issue 13

EAU – EANM – ESTRO – ESUR – ISUP – SIOG Guidelines on **Prostate Cancer**

N. Mottet (Chair), P. Cornford (Vice-chair), R.C.N. van den Bergh,

© European Association of Urology 2023

- Several of the biomarkers are pre-diagnostic

- No validated risk thresholds

- No consensus on incremental improvement in accuracy compared with clinical models

- Literature on the "clinical utility" lacks meaningful clinical outcomes

- Studies among Caucasian men

- No prospective studies have validated the use of biomarkers in the decision-making process

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Radioterapia Oncologica:
l'evoluzione al servizio dei pazienti

THE **E L D E R L Y** - THE **T R E A T M E N T**

A S S E S S

- Individual patient life expectancy and PCa natural history

- Diagnostic tools that significantly affect treatment

- Impact of therapy on survival and quality of life

- Patient preferences

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