Evropská unie
Evropský sociální fond
Operační program Zaměstnanost

Národní koordinační centrum programů časného záchytu onemocnění I CZ.03.2.63/0.0/0.0/15_039/0006904
Datová základna realizace screeningových programů CZ.03.2.63/0.0/0.0/15_039/0007216

How to implement individualised prostate cancer early detection in Czechia?

Roman Zachoval

ÚZIS Ústav zdravotnických informací a statistiky České republiky
Institute of Health Information and Statistics of the Czech Republic

MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

Review

Screening for Prostate Cancer With the Prostate-Specific Antigen Test
A Review of Current Evidence

Julia H. Hayes, MD; Michael J. Barry, MD

Table 2. Prostate Cancer Incidence and Mortality in the European Randomized Study of Screening for Prostate Cancer (ERSPC) and the Prostate, Lung, Colorectal, and Ovarian (PLCO) Screening Trial

Site	Follow-up, Median, y	Prostate Cancer Detected			Died of Prostate Cancer		
		No./Total (Cumulative Incidence %)		Rate Ratio (95% CI)	No./Total (Cumulative Incidence %)		Rate Ratio (95% CI)
		Control	Screening		Control	Screening	
ERSPC[27]							
The Netherlands	11.1	896/17390 (5.2)	2028/17443 (11.6)		97/17390 (0.56)	69/17443 (0.40)	0.71 (0.52-0.96)
Belgium	12.1	311/4255 (7.3)	420/4307 (9.8)		25/4255 (0.48)	22/4307 (0.51)	0.89 (0.48-1.52)
Sweden	14	507/5951 (8.5)	759/5901 (12.9)		70/5951 (1.18)	39/5901 (0.66)	0.56 (0.38-0.83)
Finland	11	3175/48409 (6.6)	2838/31970 (8.9)		237/48409 (0.49)	139/31970 (0.43)	0.89 (0.72-1.09)
Italy	10.7	257/7251 (3.5)	374/7266 (5.1)		22/7251 (0.30)	19/7266 (0.26)	0.86 (0.46-1.58)
Spain	10.7	24/1141 (2.1)	69/1056 (6.5)		1/1141 (0.088)	2/1056 (0.19)	2.15 (0.2-23.77)
Switzerland	8.2	226/4955 (4.6)	475/4948 (9.6)		10/4955 (0.02)	9/4948 (0.18)	0.89 (0.36-2.20)
All sites[a]	11.0	5396/89352 (6.0)	6963/72891 (9.6)	1.63 (1.57-1.69)	462/89352 (0.52)	299/72891 (0.41)	0.79 (0.68-0.91)
				Relative Risk			Relative Risk
PLCO[25]	13	3815/38345 (9.9)	4250/38340 (11.0)	1.12 (1.07-1.17)	145/38345 (0.38)	158/38340 (0.41)	1.09 (0.87-1.36)

[a]For all sites, $P = .001$.

Table 1. Screening Recommendations of Major Societies (Limited to Guidelines Based on Systematic Reviews and Updated Since the Publication of the European Randomized Study of Screening for Prostate Cancer and Prostate, Lung, Colorectal, and Ovarian Screening Trial Randomized Controlled Trials)

Organization	Who Should Be Screened	Screening Interval	Basis
US Preventive Services Task Force, 2012[14]	Screening should not be offered		Systematic review
American Urological Association, 2013[15-17]	Men aged 55-69 y or ≥70 y with >10- to 15-y life expectancy: use shared decision-making approach Men at higher risk <55 y: individualize approach	Consider 2-y interval over annual screening; may individualize intervals based on initial PSA	Systematic review and meta-analysis of the literature, 1995-2013
American Society of Clinical Oncology, 2012[18]	Men with life expectancy >10 y: use shared decision-making approach		Updating of Agency for Healthcare Research and Quality literature review; PubMed search through 2012; expert opinion
erican Cancer ciety, dated 2010[13]	Men aged >50 y at average risk with >10-y life expectancy: use shared decision-making approach Men at higher risk (black, first-degree relative diagnosed before 65 y) at 45 y Men at appreciably higher risk (multiple family members diagnosed before 65 y) at 40 y	Base interval on initial PSA: annual if ≥2.5 ng/mL; biannual if <2.5 ng/mL Biopsy recommended for all men with PSA>4 ng/mL Biopsy for PSA levels between 2.5 and 4 ng/mL should be individualized	Systematic review of the literature and consensus process
erican College of ysicians, 2013[12]	Men aged 50-69 y with life expectancy >10-15 y: use shared decision-making approach Men at higher risk (black, first-degree relative diagnosed before 65 y) at 45 y Men at appreciably higher risk (multiple family members diagnosed before 65 y) at 40 y	Consider longer intervals than 1 y between screening PSAs	Review of available guidelines
adian Urologic ciety, 2011[19]	Men ≥50 y with a 10-y life expectancy: use shared decision-making approach Men ≥40 y at high risk Consider baseline PSA in men 40-49 y	Consider intervals up to every 4 y	Systematic literature search 2004-2010
ropean Association Urology, 2013[20]	Baseline PSA≥40-45 y	Risk-adapted strategy based on initial PSA in men with life expectancy >10 y Screening intervals every 2-4 y for men with serum PSA>1.0 µg/L at 45-59 y and up to 8 y in men with serum PSA <1 µg/L	Systematic literature review and meta-analysis

CLINICAL GUIDELINE | Annals of Internal Medicine

Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement

Virginia A. Moyer, MD, PhD, on behalf of the U.S. Preventive Services Task Force*

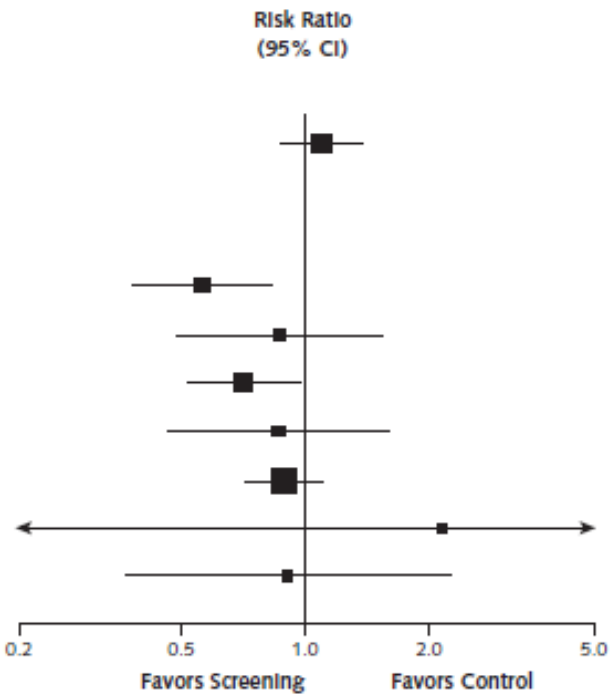
Description: Update of the 2008 U.S. Preventive Services Task Force (USPSTF) recommendation statement on screening for prostate cancer.

Methods: The USPSTF reviewed new evidence on the benefits and harms of prostate-specific antigen (PSA)–based screening for prostate cancer, as well as the benefits and harms of treatment of localized prostate cancer.

Recommendation: The USPSTF recommends against PSA-based screening for prostate cancer (grade D recommendation).

Figure 2. **Relative risk of prostate cancer death for men screened with PSA versus control participants, by country.**

Country	Screened		Control		Risk Ratio (95% CI)
	Deaths	Total	Deaths	Total	
PLCO trial					
United States	158	38 340	145	38 345	1.09 (0.87–1.36)
ERSPC trial					
Sweden	39	5901	70	5951	0.56 (0.38–0.83)
Belgium	22	4307	25	4255	0.86 (0.48–1.52)
Netherlands	69	17 443	97	17 390	0.71 (0.52–0.96)
Italy	19	7266	22	7251	0.86 (0.46–1.58)
Finland	139	31 970	237	48 409	0.89 (0.72–1.09)
Spain	2	1056	1	1141	2.15 (0.20–23.77)
Switzerland	9	4948	10	4955	0.89 (0.36–2.20)



ERSPC = European Randomized Study of Screening for Prostate Cancer; PLCO = Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial; PSA = prostate-specific antigen.

CLINICAL GUIDELINE | Annals of Internal Medicine

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Recommendation: The USPSTF recommends against PSA-based screening for prostate cancer (grade D recommendation).

This recommendation applies to men in the general U.S. population, regardless of age. This recommendation does not include the use of the PSA test for surveillance after diagnosis or treatment of prostate cancer; the use of the PSA test for this indication is outside the scope of the USPSTF.

SCREENING FOR PROSTATE CANCER

CLINICAL SUMMARY OF U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

Population	**Adult Males**
Recommendation	**Do not use prostate-specific antigen (PSA)–based screening for prostate cancer.**
	Grade: D

Screening Tests	Contemporary recommendations for prostate cancer screening all incorporate the measurement of serum PSA levels; other methods of detection, such as digital rectal examination or ultrasonography, may be included. There is convincing evidence that PSA-based screening programs result in the detection of many cases of asymptomatic prostate cancer, and that a substantial percentage of men who have asymptomatic cancer detected by PSA screening have a tumor that either will not progress or will progress so slowly that it would have remained asymptomatic for the man's lifetime (i.e., PSA-based screening results in considerable overdiagnosis).
Interventions	Management strategies for localized prostate cancer include watchful waiting, active surveillance, surgery, and radiation therapy. There is no consensus regarding optimal treatment.
Balance of Harms and Benefits	The reduction in prostate cancer mortality 10 to 14 years after PSA-based screening is, at most, very small, even for men in the optimal age range of 55 to 69 years. The harms of screening include pain, fever, bleeding, infection, and transient urinary difficulties associated with prostate biopsy, psychological harm of false-positive test results, and overdiagnosis. Harms of treatment include erectile dysfunction, urinary incontinence, bowel dysfunction, and a small risk for premature death. Because of the current inability to reliably distinguish tumors that will remain indolent from those destined to be lethal, many men are being subjected to the harms of treatment for prostate cancer that will never become symptomatic. The benefits of PSA-based screening for prostate cancer do not outweigh the harms.
Other Relevant USPSTF Recommendations	Recommendations on screening for other types of cancer can be found at www.uspreventiveservicestaskforce.org.

For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statement, and supporting documents, please go to www.uspreventiveservicestaskforce.org.

Table 3. **PSA-Based Screening for Prostate Cancer***

Why not screen for prostate cancer?
Screening may benefit a small number of men but will result in harm to many others. A person choosing to be screened should believe that the possibility of benefit is more important than the risk for harm. The USPSTF assessment of the balance of benefits and harms in a screened population is that the benefits do not outweigh the harms.

What are the benefits and harms of screening 1000 men aged 55–69 y† with a PSA test every 1–4 y for 10 y?

Possible benefit of screening	Men, *n*
Reduced 10 y risk for dying of prostate cancer	
Die of prostate cancer with no screening	5 in 1000
Die of prostate cancer with screening	4–5 in 1000
Do not die of prostate cancer because of screening	0–1 in 1000
Harms of screening	
At least 1 false-positive screening PSA test result	
Most positive test results lead to biopsy. Of men having biopsy, up to 33% will have moderate or major bothersome symptoms, including pain, fever, bleeding, infection, and temporary urinary difficulties; 1% will be hospitalized.	100–120 in 1000
Prostate cancer diagnosis	
Although a diagnosis of prostate cancer may not be considered a harm, currently 90% of diagnosed men are treated and, thus, are at risk for the harms of treatment. A large majority of the men who are being treated would do well without treatment. A substantial percentage of these men would have remained asymptomatic for life.	110 in 1000
Complications of treatment (among persons who are screened)‡	
Develop serious cardiovascular events due to treatment	2 in 1000
Develop deep venous thrombosis or pulmonary embolus due to treatment	1 in 1000
Develop erectile dysfunction due to treatment	29 in 1000
Develop urinary incontinence due to treatment	18 in 1000
Die due to treatment	<1 in 1000

PSA = prostate-specific antigen.
* The table design is adapted from Woloshin and Schwartz (14). Calculations of the estimated benefits and harms rely on assumptions and are, by nature, somewhat imprecise. Estimates should be considered in the full context of clinical decision making and used to stimulate shared decision making.
† The best evidence of possible benefit of PSA screening is in men aged 55–69 y.
‡ The rate of complications depends on the proportion of men having treatment and the method of treatment. The table reflects a distribution of 60% surgical treatment, 30% radiation, and 10% observation (see **Appendix 2**, available at www.annals.org, for more details about assumptions and references). Other harms of radiation, such as bowel damage, are not shown.

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BMC Medicine

Spotlight on prostate cancer

COMMENTARY Open Access

Prostate-specific antigen-based screening: controversy and guidelines

Eric H Kim and Gerald L Andriole*

Table 1 Summary of PSA screening guidelines by organization

Organization	Year published	Baseline testing (age)	Invitation to screening* (age)	High risk groups** (age)	Screening interval
American Cancer Society [23]	2010	None	Beginning at 50 years while life expectancy ≥ 10 years	Beginning at 40 years while life expectancy ≥ 10 years	- Annually if PSA ≥ 2.5 ng/mL - Every 2 years if PSA < 2.5 ng/mL
U.S. Preventive Services Task Force [24]	2012	None	None	None	None
American Urological Association [25]	2013	None	55 - 69 years	40 - 69 years	Every 2 years
European Association of Urology [26]	2013	40 - 45 years	Any age while life expectancy ≥ 10 years	Any age while life expectancy ≥ 10 years	- Every 2 to 4 years if baseline PSA > 1 ng/mL - Every 8 years if baseline PSA ≤ 1 ng/mL
American College of Physicians [27]	2013	None	50 - 69 years	40 - 69 years	Annually if PSA ≥ 2.5 ng/mL
National Comprehensive Cancer Network [28]	2014	45 - 49 years	50 - 70 years 70 - 75 years if life expectancy ≥ 10 years	Consider change in biopsy threshold	For 40 - 49 years: - Every 1 - 2 years if PSA > 1 ng/mL - Repeat at age 50 if PSA ≤ 1 ng/mL For 50 - 70 years: - Every 1 - 2 years
Melbourne Consensus Statement [29]	2014	40 - 49 years	50 - 69 years 70+ years while life expectancy ≥ 10 years	Use to better risk stratify men	None specified

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Screening and Prostate-Cancer Mortality in a Randomized European Study

Fritz H. Schröder, M.D., Jonas Hugosson, M.D., Monique J. Roobol, Ph.D., Teuvo L.J. Tammela, M.D., Stefano Ciatto, M.D., Vera Nelen, M.D., Maciej Kwiatkowski, M.D., Marcos Lujan, M.D., Hans Lilja, M.D., Marco Zappa, Ph.D., Louis J. Denis, M.D., Franz Recker, M.D., Antonio Berenguer, M.D., Liisa Määttänen, Ph.D., Chris H. Bangma, M.D., Gunnar Aus, M.D., Arnauld Villers, M.D., Xavier Rebillard, M.D., Theodorus van der Kwast, M.D., Bert G. Blijenberg, Ph.D., Sue M. Moss, Ph.D., Harry J. de Koning, M.D., and Anssi Auvinen, M.D., for the ERSPC Investigators*

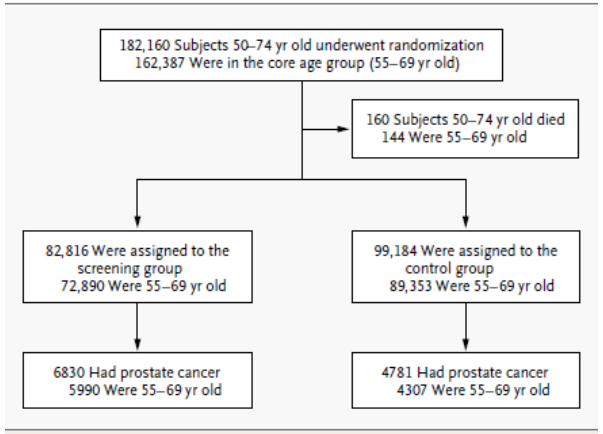

Figure 1. Enrollment and Outcomes, According to Age Group at Randomization.
The predefined core age group for this study included 162,243 men between the ages of 55 and 69 years.

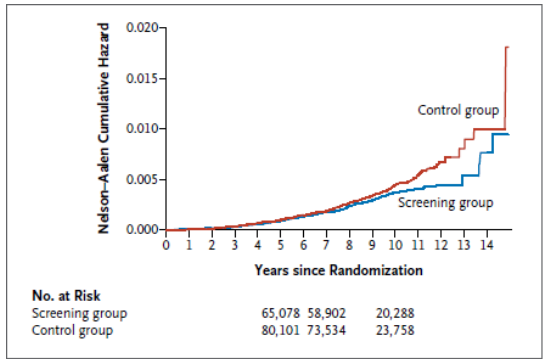

Figure 2. Cumulative Risk of Death from Prostate Cancer.
As of December 31, 2006, with an average follow-up time of 8.8 years, there were 214 prostate-cancer deaths in the screening group and 326 in the control group. Deaths that were associated with interventions were categorized as being due to prostate cancer. The adjusted rate ratio for death from prostate cancer in the screening group was 0.80 (95% CI, 0.65 to 0.98; P=0.04). The Nelsen–Aalen method was used for the calculation of cumulative hazard.

Table 2. Death from Prostate Cancer, According to the Age at Randomization.*

Age at Randomization	Screening Group		Control Group		Rate Ratio (95% CI)†
	No. of Deaths	Person-Yr (Death Rate per 1000 Person-Yr)	No. of Deaths	Person-Yr (Death Rate per 1000 Person-Yr)	
All subjects	261	737,397 (0.35)	363	878,547 (0.41)	0.85 (0.73–1.00)
Age group					
50–54 yr	6	55,241 (0.11)	4	53,734 (0.07)	1.47 (0.41–5.19)
55–59 yr	60	316,389 (0.19)	102	402,062 (0.25)	0.73 (0.53–1.00)
60–64 yr	76	191,542 (0.40)	95	221,113 (0.43)	0.94 (0.69–1.27)
65–69 yr	78	135,470 (0.58)	129	162,410 (0.79)	0.74 (0.56–0.99)
70–74 yr	41	38,755 (1.06)	33	39,228 (0.84)	1.26 (0.80–1.99)

* The result of the chi-square test for heterogeneity among subjects in the core age group (55 to 69 years) was 2.44 (P=0.49).
† Rate ratios were calculated with the use of Poisson regression and compare the rate of death from prostate cancer in the screening group with the rate in the control group.

Table 3. Rate Ratios for Death from Any Cause and Death from Prostate Cancer, with Exclusions According to Location of Study Center.*

Variable	Rate Ratio (95% CI)	P Value†
All deaths from any cause	0.99 (0.97–1.02)	0.50
All deaths from prostate cancer	0.80 (0.67–0.95)	0.01
Excluding the Netherlands	0.81 (0.67–0.99)	0.04
Excluding Finland	0.74 (0.58–0.94)	0.01
Excluding Sweden	0.84 (0.70–1.01)	0.06
Excluding Belgium	0.79 (0.66–0.94)	0.01
Excluding Spain	0.79 (0.67–0.94)	0.01
Excluding Italy	0.79 (0.66–0.94)	0.01
Excluding Switzerland	0.80 (0.68–0.96)	0.02

* Rate ratios, which were calculated with the use of Poisson regression, compare the rate of death from prostate cancer in the screening group with the rate in the control group. The calculations were restricted to men in the core age group (55 to 69 years).
† P values have not been corrected for multiple testing.

Mortality results from the Göteborg randomised population-based prostate-cancer screening trial

Jonas Hugosson, Sigrid Carlsson, Gunnar Aus, Svante Bergdahl, Ali Khatami, Pär Lodding, Carl-Gustaf Pihl, Johan Stranne, Erik Holmberg, Hans Lilja

Summary

Background Prostate cancer is one of the leading causes of death from malignant disease among men in the developed world. One strategy to decrease the risk of death from this disease is screening with prostate-specific antigen (PSA); however, the extent of benefit and harm with such screening is under continuous debate.

Methods In December, 1994, 20 000 men born between 1930 and 1944, randomly sampled from the population register, were randomised by computer in a 1:1 ratio to either a screening group invited for PSA testing every 2 years (n=10 000) or to a control group not invited (n=10 000). Men in the screening group were invited up to the upper age limit (median 69, range 67–71 years) and only men with raised PSA concentrations were offered additional tests such as digital rectal examination and prostate biopsies. The primary endpoint was prostate-cancer specific mortality, analysed according to the intention-to-screen principle. The study is ongoing, with men who have not reached the upper age limit invited for PSA testing. This is the first planned report on cumulative prostate-cancer incidence and mortality calculated up to Dec 31, 2008. This study is registered as an International Standard Randomised Controlled Trial ISRCTN54449243.

Findings In each group, 48 men were excluded from the analysis because of death or emigration before the randomisation date, or prevalent prostate cancer. In men randomised to screening, 7578 (76%) of 9952 attended at least once. During a median follow-up of 14 years, 1138 men in the screening group and 718 in the control group were diagnosed with prostate cancer, resulting in a cumulative prostate-cancer incidence of 12·7% in the screening group and 8·2% in the control group (hazard ratio 1·64; 95% CI 1·50–1·80; p<0·0001). The absolute cumulative risk reduction of death from prostate cancer at 14 years was 0·40% (95% CI 0·17–0·64), from 0·90% in the control group to 0·50% in the screening group. The rate ratio for death from prostate cancer was 0·56 (95% CI 0·39–0·82; p=0·002) in the screening compared with the control group. The rate ratio of death from prostate cancer for attendees compared with the control group was 0·44 (95% CI 0·28–0·68; p=0·0002). Overall, 293 (95% CI 177–799) men needed to be invited for screening and 12 to be diagnosed to prevent one prostate cancer death.

Interpretation This study shows that prostate cancer mortality was reduced almost by half over 14 years. However, the risk of over-diagnosis is substantial and the number needed to treat is at least as high as in breast-cancer screening programmes. The benefit of prostate-cancer screening compares favourably to other cancer screening programs.

Funding The Swedish Cancer Society, the Swedish Research Council, and the National Cancer Institute.

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See Reflection and Reaction page 702

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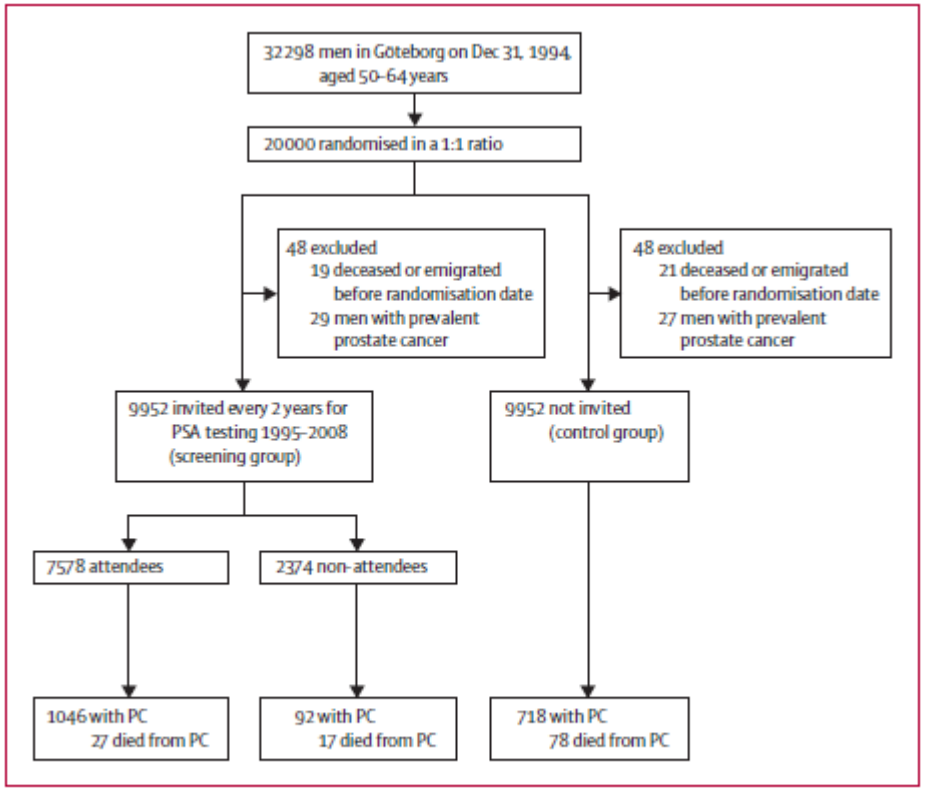

Figure 1: **Trial profile**
PSA=prostate-specific antigen. PC=prostate cancer.

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See Reflection and Reaction page 702

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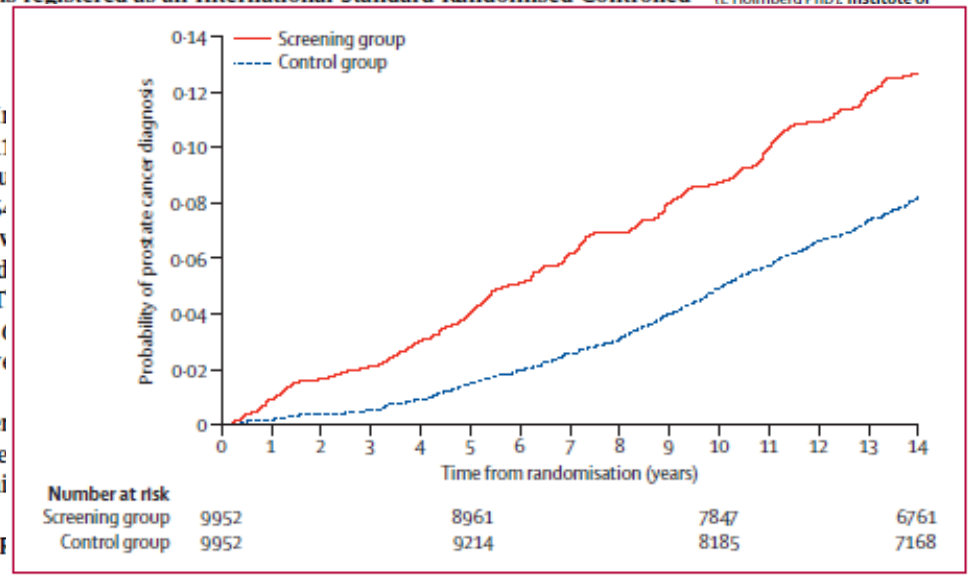

Figure 2: Cumulative incidence of prostate cancer in the screening group and in the control group

	Control group (n=9952)	Screening group (n=9952)		
		All (n=9952)	Attendees (n=7578)	Non-attendees (n=2374)
Number of men with prostate cancers diagnosed (%)	718 (7·2%)	1138 (11·4%)	1046 (13·8%)	92 (3·9%)
Tumour grouping (%)				
Low risk*	199 (2%)	604 (6·1%)	590 (7·8%)	14 (0·6%)
Moderate risk†	249 (2·5%)	363 (3·6%)	339 (4·5%)	24 (1%)
High risk‡	126 (1·3%)	96 (1%)	76 (1%)	20 (0·8%)
Advanced disease§	87 (0·9%)	46 (0·5%)	25 (0·3%)	21 (0·9%)
Unknown¶	57 (0·6%)	29 (0·3%)	16 (0·2%)	13 (0·5%)

*T1, not N1 or M1, and Gleason score ≤6 and prostate-specific antigen <10 ng/mL. †T1–2, but not N1 or M1, with a Gleason score ≤7, prostate-specific antigen <20 ng/mL or both; and not meeting the criteria for low risk. ‡T1–4, but not N1 or M1, with a Gleason score ≥8, prostate-specific antigen <100 ng/mL, or both; and not meeting the criteria for low or moderate risk. §N1 or M1, or prostate-specific antigen ≥100 ng/mL. ¶Includes seven cases detected at autopsy.

Table 2: Prostate cancers diagnosed in the study groups

	Control group (n=718)	Screening group (n=1138)		
		All (n=1138)	Attendees (n=1046)	Non-attendees (n=92)
Primary radical prostatectomy*	241 (33·6%)	468 (41·1%)	439 (42·0%)	29 (31·5%)
Primary radiation	75 (10·4%)	93 (8·2%)	81 (7·7%)	12 (13·0%)
Primary endocrine treatment	162 (22·6%)	80 (7·0%)	47 (4·5%)	33 (35·9%)
Primary surveillance followed by curative treatment†	36 (5·0%)	142 (12·5%)	141 (13·5%)	1 (1·1%)
Primary surveillance followed by endocrine treatment	20 (2·8%)	23 (2·0%)	21 (2·0%)	2 (2·2%)
Surveillance at last follow-up	152 (21·2%)	314 (27·6%)	301 (28·8%)	13 (14·1%)
Not treated‡	32 (4·5%)	18 (1·6%)	16 (1·5%)	2 (2·2%)

Data are n (%). *Includes nine cryosurgeries and six cystoprostatectomies. †Includes two cystoprostatectomies. ‡Includes seven cases detected at autopsy.

Table 3: Treatments for prostate cancer, by study group

Mortality results from the Göteborg randomised population-based prostate-cancer screening trial

Jonas Hugosson, Sigrid Carlsson, Gunnar Aus, Svante Bergdahl, Ali Khatami, Pär Lodding, Carl-Gustaf Pihl, Johan Stranne, Erik Holmberg, Hans Lilja

Summary

Background Prostate cancer is one of the leading causes of death from malignant disease among men in the developed world. One strategy to decrease the risk of death from this disease is screening with prostate-specific antigen (PSA); however, the extent of benefit and harm with such screening is under continuous debate.

Methods In December, 1994, 20 000 men born between 1930 and 1944, randomly sampled from the population register, were randomised by computer in a 1:1 ratio to either a screening group invited for PSA testing every 2 years (n=10 000) or to a control group not invited (n=10 000). Men in the screening group were invited up to the upper age limit (median 69, range 67–71 years) and only men with raised PSA concentrations were offered additional tests such as digital rectal examination and prostate biopsies. The primary endpoint was prostate-cancer specific mortality, analysed according to the intention-to-screen principle. The study is ongoing, with men who have not reached the upper age limit invited for PSA testing. This is the first planned report on cumulative prostate-cancer incidence and mortality calculated up to Dec 31, 2008. This study is registered as an International Standard Randomised Controlled Trial ISRCTN54449243.

Findings In each group, 48 men were excluded from the analysis because of death or emigration before the randomisation date, or prevalent prostate cancer. In men randomised to screening, 7578 (76%) of 9952 attended at least once. During a median follow-up of 14 years, 1138 men in the screening group and 718 in the control group were diagnosed with prostate cancer, resulting in a cumulative prostate-cancer incidence of 12·7% in the screening group and 8·2% in the control group (hazard ratio 1
reduction of death from prostate cancer at 14 year
to 0·50% in the screening group. The rate ratio fo
in the screening compared with the control group
with the control group was 0·44 (95% CI 0·28–
invited for screening and 12 to be diagnosed to pr

Interpretation This study shows that prostate can
risk of over-diagnosis is substantial and the num
programmes. The benefit of prostate-cancer scre

Funding The Swedish Cancer Society, the Swedis

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See Reflection and Reaction page 702

Department of Urology (Prof J Hugosson MD, S Carlsson MD, G Aus MD, S Bergdahl MD, A Khatami MD, P Lodding MD, J Stranne MD), and Oncology (E Holmberg PhD), Institute of Clinical Sciences, Sahlgrenska Academy at University of Göteborg, Sweden; Department of Pathology, Institute of Biomedicine, Sahlgrenska Academy at University of Göteborg,

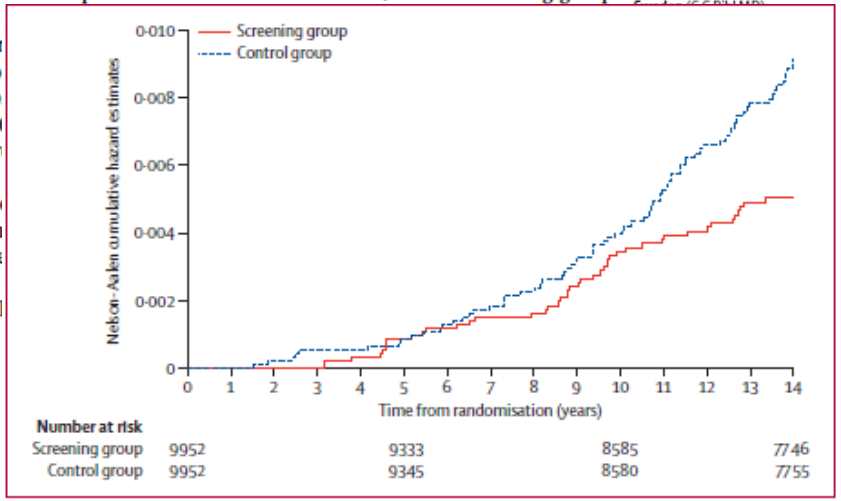

Figure 3: Cumulative risk of death from prostate cancer using Nelson-Aalen cumulative hazard estimates

	Total	Control group	Screening group		
			All	Attendees	Non-attendees
1930–34					
Total number	5563	2789	2774	2064	710
Number with PC	615	259	356	318	38
Number of deaths	1689	853	836	488	348
Number of PC deaths	62	35	27	19	8
1935–39					
Total number	6284	3161	3123	2420	703
Number with PC	654	252	402	372	30
Number of deaths	1284	650	634	360	274
Number of PC deaths	47	35	12	6	6
1940–44					
Total number	8057	4002	4055	3094	961
Number with PC	587	207	380	356	24
Number of deaths	990	479	511	267	244
Number of PC deaths	13	8	5	2	3
Total					
Total number	19 904	9952	9952	7578	2374
Number with PC	1856	718	1138	1046	92
Number of deaths	3963	1982	1981	1115	866
Number of PC deaths	122	78	44	27	17

PC=prostate cancer.

Table 4: Outcome of men in relation to birth cohort at entry to the study

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European Association of Urology

Platinum Priority – Prostate Cancer – Editor's Choice

Editorial by Gunnar Steineck, Olof Akre and Anna Bill-Axelson on pp. 52–53 of this issue

A 16-yr Follow-up of the European Randomized study of Screening for Prostate Cancer

Jonas Hugosson [a,], Monique J. Roobol [b], Marianne Månsson [a], Teuvo L.J. Tammela [c], Marco Zappa [d], Vera Nelen [e], Maciej Kwiatkowski [f,g], Marcos Lujan [h], Sigrid V. Carlsson [a,i], Kirsi M. Talala [j], Hans Lilja [k,l,m,n,o], Louis J. Denis [p], Franz Recker [f], Alvaro Paez [q], Donella Puliti [d], Arnauld Villers [r], Xavier Rebillard [s], Tuomas P. Kilpeläinen [t], Ulf H. Stenman [u], Rebecka Arnsrud Godtman [a], Karin Stinesen Kollberg [a], Sue M. Moss [v], Paula Kujala [u], Kimmo Taari [t], Andreas Huber [w], Theodorus van der Kwast [x], Eveline A. Heijnsdijk [y], Chris Bangma [b], Harry J. De Koning [y], Fritz H. Schröder [b], Anssi Auvinen [z], on behalf of the ERSPC investigators*

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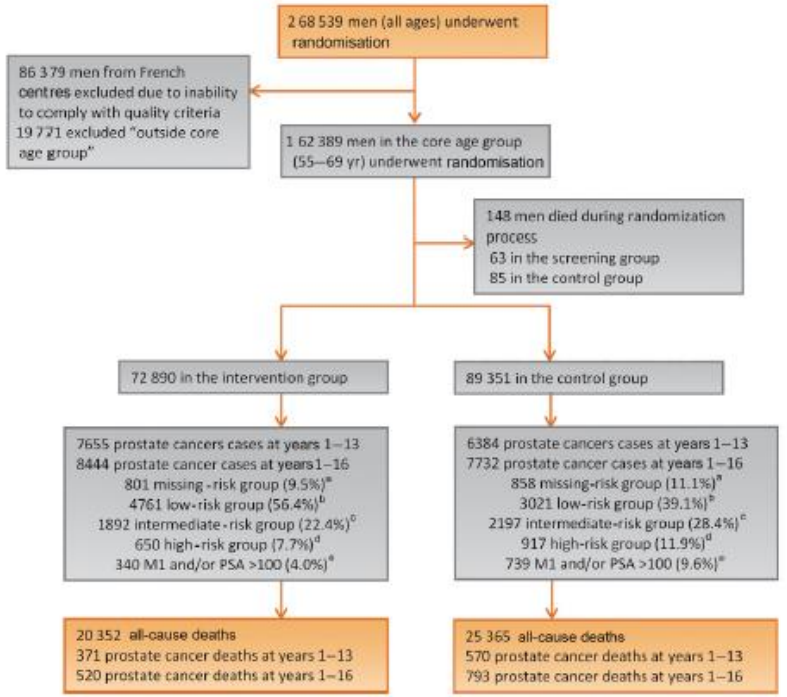

Fig. 1 – Trial profile (core age group). GS = Gleason score; M1 = evidence of metastases on imaging or PSA >100 ng/ml; PSA = prostate-specific antigen. [a] Missing = missing T stage or GS, not M1 or PSA >100. [b] Low risk = T1, and T1 with GS ≤6. [c] Intermediate risk = T1, and T2 with GS 7 and T3 with GS ≤7. [d] High risk = T1, T2, and T3 with GS 8–10 and T4 with any GS. [e] M1 or PSA >100, any T stage, or GS.

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Platinum Priority – Prostate Cancer – Editor's Choice

Editorial by Gunnar Steineck, Olof Akre and Anna Bill-Axelson on pp. 52–53 of this issue

A 16-yr Follow-up of the European Randomized study of Screening for Prostate Cancer

Jonas Hugosson[a,], Monique J. Roobol[b], Marianne Månsson[a], Teuvo L.J. Tammela[c], Marco Zappa[d], Vera Nelen[e], Maciej Kwiatkowski[f,g], Marcos Lujan[h], Sigrid V. Carlsson[a,i], Kirsi M. Talala[j], Hans Lilja[k,l,m,n,o], Louis J. Denis[p], Franz Recker[f], Alvaro Paez[q], Donella Puliti[d], Arnauld Villers[r], Xavier Rebillard[s], Tuomas P. Kilpeläinen[t], Ulf H. Stenman[u], Rebecka Arnsrud Godtman[a], Karin Stinesen Kollberg[a], Sue M. Moss[v], Paula Kujala[u], Kimmo Taari[t], Andreas Huber[w], Theodorus van der Kwast[x], Eveline A. Heijnsdijk[y], Chris Bangma[b], Harry J. De Koning[y], Fritz H. Schröder[b], Anssi Auvinen[z], on behalf of the ERSPC investigators*

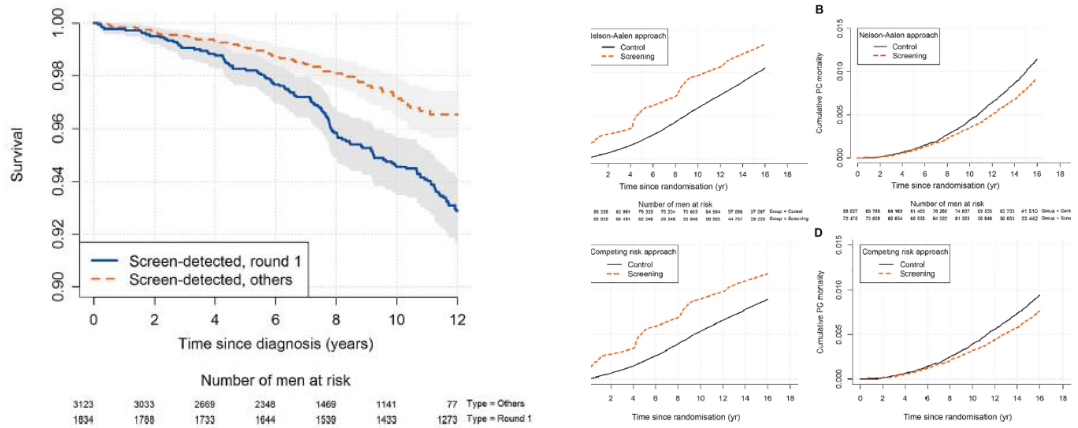

Fig. 3 – Prostate cancer-specific survival in those detected during round 1 screening and those detected during repeated screening. ncer incidence estimated by (A) the Nelson-Aalen approach and (C) the competing risk approach, and prostate cancer-specific d by (B) the Nelson-Aalen approach and (D) the competing risk approach. PC = prostate cancer.

Table 2 – Prostate cancer incidence at various lengths of follow-up

	Years 1–9	Years 1–11	Years 1–13	Years 1–16
Screening group				
Prostate cancer (*n*)	6172	6852	7655	8444
Person years	584 776	695 850	797 774	918 300
Rate per 1000 person years	10.55	9.85	9.60	9.20
Risk per 1000 men	85.16	94.54	105.62	116.51
Control group				
Prostate cancer (*n*)	4154	5333	6384	7732
Person years	735 777	877 302	1 007 337	1 162 062
Rate per 1000 person years	5.65	6.08	6.34	6.65
Risk per 1000 men	46.71	59.97	71.79	86.95
Rate ratio (95% CI)	1.90 (1.83–1.98)	1.65 (1.59–1.71)	1.54 (1.49–1.59)	1.41 (1.36–1.45)
Rate difference per 1000 person years (95% CI)	5.00 (4.69–5.31)	3.86 (3.58–4.14)	3.35 (3.09–3.61)	2.66 (2.42–2.90)
Risk ratio (95% CI)	1.85 (1.78–1.93)	1.60 (1.54–1.66)	1.49 (1.44–1.54)	1.36 (1.32–1.41)
Risk difference per 1000 men (95% CI)	39.15 (36.65–41.65)	35.41 (32.71–38.12)	34.82 (31.93–37.72)	31.15 (28.05–34.25)

CI = confidence interval.

Table 3 – Prostate cancer mortality at various lengths of follow-up

	Years 1–9	Years 1–11	Years 1–13	Years 1–16
Screening group				
Prostate cancer deaths (*n*)	191	268	371	520
Person years	612 723	735 205	848 802	985 382
Rate per 1000 person years	0.31	0.36	0.44	0.53
Risk per 1000 men	2.64	3.70	5.12	7.17
Control group				
Prostate cancer deaths (*n*)	280	419	570	793
Person years	749 801	899 370	1 038 723	1 207 411
Rate per 1000 person years	0.37	0.47	0.55	0.66
Risk per 1000 men	3.15	4.71	6.41	8.92
Rate ratio (95% CI)	0.84 (0.70–1.00)	0.78 (0.67–0.91)	0.79 (0.69–0.90)	0.80 (0.72–0.89)
p value	0.053	0.001	<0.001	<0.001
Rate difference per 1000 person years (95% CI)	−0.06 (−0.12 to 0.00)	−0.10 (−0.17 to −0.04)	−0.12 (−0.18 to −0.05)	−0.13 (−0.20 to −0.07)
Rate ratio, attenders	0.78 (0.63, 0.96)	0.72 (0.60, 0.86)	0.73 (0.63, 0.85)	0.75 (0.66, 0.85)
p value	0.022	<0.001	<0.001	<0.001
Risk ratio (95% CI)	0.84 (0.70–1.00)	0.78 (0.67–0.91)	0.79 (0.70–0.90)	0.80 (0.72–0.90)
Risk difference per 1000 men (95% CI)	−0.51 (−1.04 to 0.01)	−1.04 (−1.67 to −0.41)	−1.35 (−2.09 to −0.61)	−1.76 (−2.63 to −0.88)
NNI (95% CI)	1947 (963–inf)	962 (598–2463)	742 (478–1650)	570 (380–1137)
NND	76	34	26	18

CI = confidence interval; inf = infinity; NND = number needed to invite to diagnose to prevent one prostate cancer death; NNI = number needed to invite to screening to prevent one prostate cancer death.

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NÁRODNÍ SCREENINGOVÉ CENTRUM

ÚZIS ČR

MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

The effect of the USPSTF PSA screening recommendation on prostate cancer incidence patterns in the USA

Katherine Fleshner[1], Sigrid V. Carlsson[2,3] and Monique J. Roobol[4]

Abstract | Guidelines regarding recommendations for PSA screening for early detection of prostate cancer are conflicting. In 2012, the United States Preventive Services Task Force (USPSTF) assigned a grade of D (recommending against screening) for men aged ≥75 years in 2008 and for men of all ages in 2012. Understanding temporal trends in rates of screening before and after the 2012 recommendation in terms of usage patterns in PSA screening, changes in prostate cancer incidence and biopsy patterns, and how the recommendation has influenced physician's and men's attitudes about PSA screening and subsequent ordering of other screening tests is essential within the scope of prostate cancer screening policy. Since the 2012 recommendation, rates of PSA screening decreased by 3–10% in all age groups and across most geographical regions of the USA. Rates of prostate biopsy and prostate cancer incidence have declined in unison, with a shift towards tumours being of higher grade and stage upon detection. Despite the recommendation, some physicians report ongoing willingness to screen appropriately selected men, and many men report intending to continue to ask for the PSA test from their physician. In the coming years, we expect to have an improved understanding of whether these decreased rates of screening will affect prostate cancer metastasis and mortality.

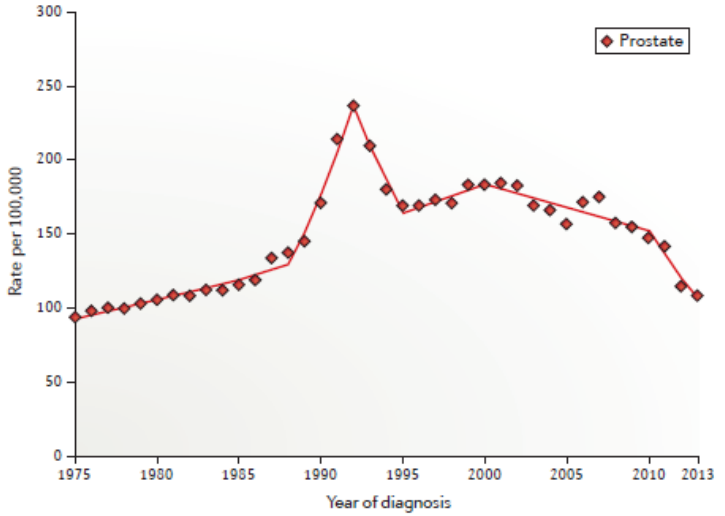


Figure 1 | **Age-adjusted prostate cancer incidence rates in men of all races between 1975 and 2013**. The graph reflects the effect of the availability and use of the PSA test on early detection and diagnosis of prostate cancer from the SEER 9 Database. Rates are per 100,000 and age-adjusted to the 2000 US standard population. The figure is extracted with permission from the SEER Database.

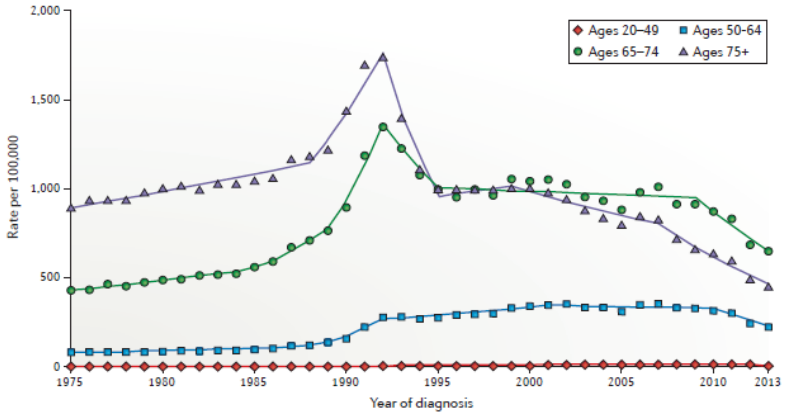


Figure 2 | **Age-adjusted prostate cancer incidence rates in the Surveillance, Epidemiology and End Results (SEER) database by age at diagnosis from 1975 to 2013 in the USA.** Trends in the graph are similar to those depicted in FIG. 1, but the effect of the use of the PSA test is most noticeable in men aged >65 years from the SEER 9 Database. Rates are per 100,000 and age-adjusted to the 2000 US standard population. The figure is extracted with permission from the SEER Database.

Annals of Internal Medicine

ORIGINAL RESEARCH

Reconciling the Effects of Screening on Prostate Cancer Mortality in the ERSPC and PLCO Trials

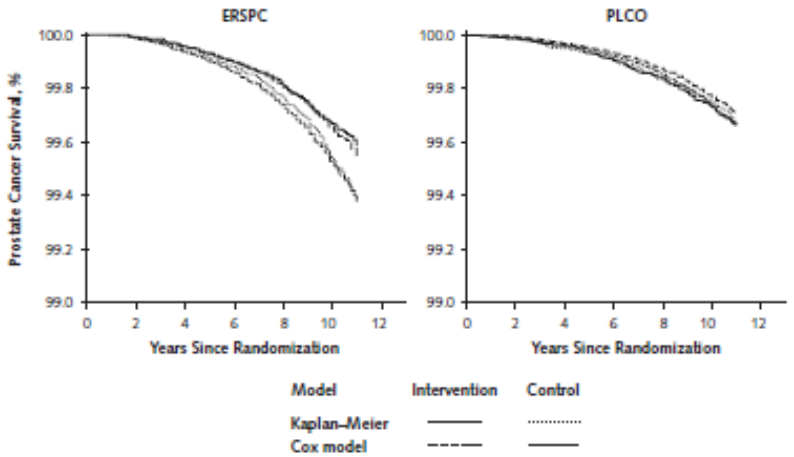
Alex Tsodikov, PhD; Roman Gulati, MS; Eveline A.M. Heijnsdijk, PhD; Paul F. Pinsky, PhD; Sue M. Moss, PhD; Sheng Qiu, MS; Tiago M. de Carvalho, MS; Jonas Hugosson, MD; Christine D. Berg, MD; Anssi Auvinen, MD; Gerald L. Andriole, MD; Monique J. Roobol, PhD; E. David Crawford, MD; Vera Nelen, MD; Maciej Kwiatkowski, MD; Marco Zappa, PhD; Marcos Luján, MD; Arnauld Villers, MD; Eric J. Feuer, PhD; Harry J. de Koning, MD; Angela B. Mariotto, PhD; and Ruth Etzioni, PhD

Table 1. Summary of Participant Characteristics, Follow-up, and Prostate Cancer Cases and Deaths in the ERSPC and PLCO, Under All Available Follow-up and Restricted to 11 Years of Follow-up

Characteristic	ERSPC		PLCO	
	Control	Screening	Control	Screening
Participants, *n*	88 921	72 473	38 343	38 340
Median age at randomization (range), *y*	59 (55–69)	60 (55–69)	62 (55–74)	62 (55–74)
All available follow-up				
Median follow-up from randomization (range), *y*	11.0 (0.4–17.5)	11.1 (0.4–17.3)	12.5 (0–13.0)	12.5 (0–13.0)
Prostate cancer cases, *n*	5398	6967	4040	4430
Person-years of follow-up for incidence	933 854	740 775	403 955	400 008
Deaths, *n*	17 019	13 652	7149	6940
Other causes	16 557	13 353	7003	6788
Prostate cancer	462	299	146	152
Person-years of follow-up for mortality	990 678	827 148	426 720	427 824
Restricted to 11 y of follow-up				
Median follow-up from randomization (range), *y*	11.0 (0.4–11.0)	11.0 (0.4–11.0)	11.0 (0–11.0)	11.0 (0–11.0)
Prostate cancer cases, *n*	4961	6586	3641	4038
Person-years of follow-up for incidence	868 834	686 766	368 844	365 129
Deaths, *n*	13 207	10 397	5880	5798
Other causes	12 822	10 150	5771	5687
Prostate cancer	385	247	109	111
Person-years of follow-up for mortality	890 581	725 997	387 027	387 861

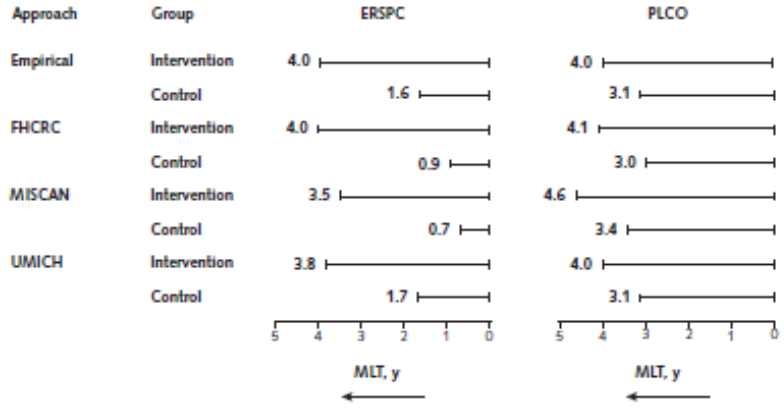
ERSPC = European Randomized Study of Screening for Prostate Cancer; PLCO = Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial.

Figure 2. Prostate cancer survival from randomization in the ERSPC and PLCO, estimated by Kaplan-Meier or Cox regression model using mean lead time estimated with the empirical approach.



ERSPC = European Randomized Study of Screening for Prostate Cancer; PLCO = Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial.

Figure 1. Estimated MLTs in the intervention and control groups of the ERSPC and PLCO relative to a hypothetical no-screening setting (where MLT equals zero).



Estimated MLTs are visualized as increasing to the left to suggest the extent to which prostate cancer diagnosis is advanced by more intensive screening and diagnostic work-up. ERSPC = European Randomized Study of Screening for Prostate Cancer; FHCRC = Fred Hutchinson Cancer Research Center; MISCAN = Erasmus University Medical Center MIcrosimulation SCreening ANalysis; MLT = mean lead time; PLCO = Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial; UMICH = University of Michigan.

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European Association of Urology

Review – Prostate Cancer – Editor's Choice

Prostate-specific Antigen Testing as Part of a Risk-Adapted Early Detection Strategy for Prostate Cancer: European Association of Urology Position and Recommendations for 2021

Hendrik Van Poppel [a,*], *Monique J. Roobol* [b], *Christopher R. Chapple* [c], *James W.F. Catto* [d,e], *James N'Dow* [f,g], *Jens Sønksen* [h,i], *Arnulf Stenzl* [j], *Manfred Wirth* [k]

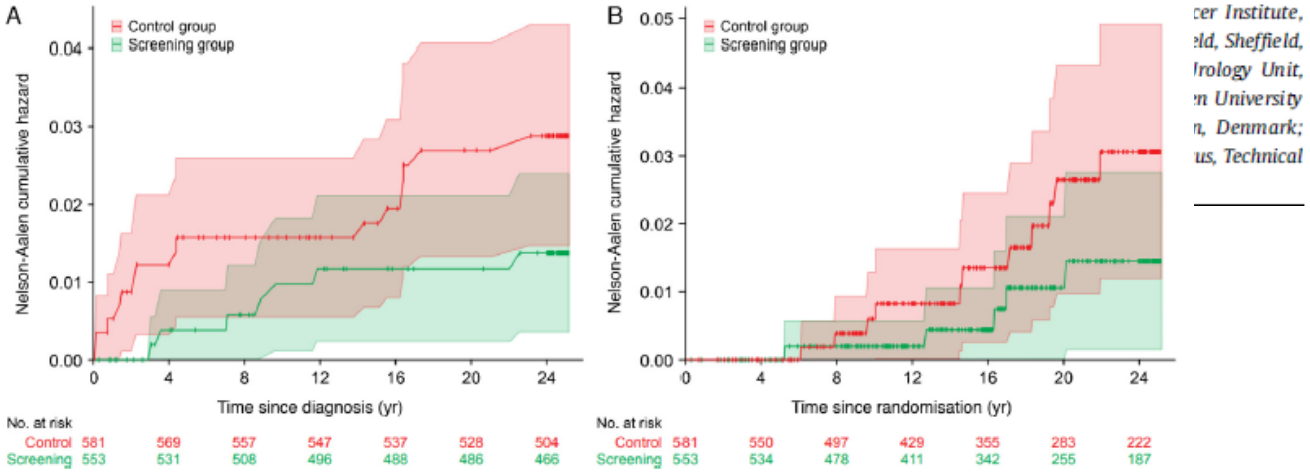

Fig. 1 – Reduction in (A) progression to M+ prostate cancer (54%) and (B) prostate cancer–specific mortality (52%) due to PSA screening in the Rotterdam cohort (n = 1134) of ERSPC at 19 yr of follow-up [2].
ERSPC = European Randomised study of Screening for Prostate Cancer; M+ = metastatic; PSA = prostate-specific antigen.

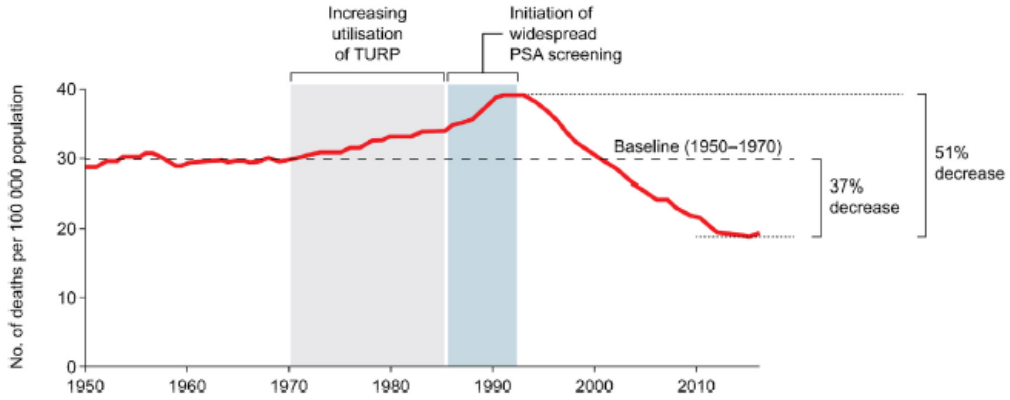

Fig. 2 – Prostate cancer–specific mortality rates in the USA from 1950 to 2019 [8].
PSA = prostate-specific antigen; TURP = transurethral resection of the prostate.
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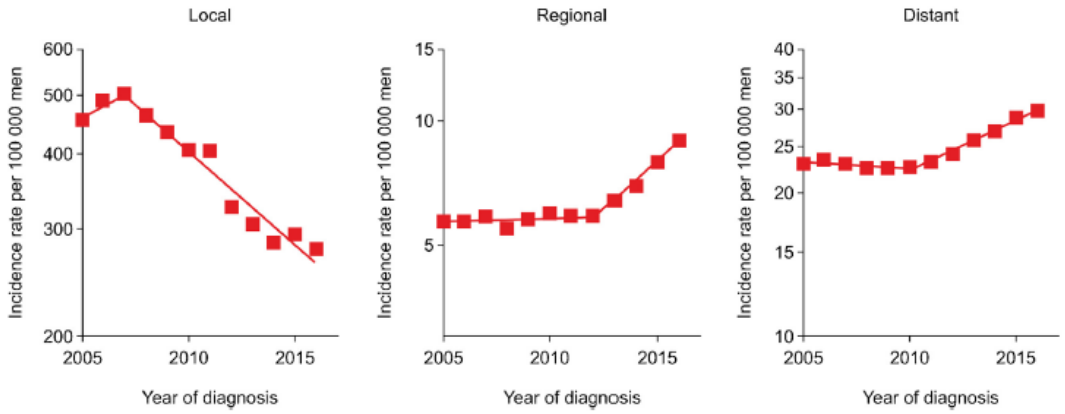

Fig. 3 – Stage migration in prostate cancer diagnoses in the USA after the USPSTF recommendations against PSA screening in 2012 [14].
PSA = prostate-specific antigen; USPSTF = United States Preventive Service Task Force.
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European Association of Urology

Review – Prostate Cancer – Editor's Choice

Prostate-specific Antigen Testing as Part of a Risk-Adapted Early Detection Strategy for Prostate Cancer: European Association of Urology Position and Recommendations for 2021

Hendrik Van Poppel[a,*], *Monique J. Roobol*[b], *Christopher R. Chapple*[c], *James W.F. Catto*[d,e], *James N'Dow*[f,g], *Jens Sønksen*[h,i], *Arnulf Stenzl*[j], *Manfred Wirth*[k]

[a] *Department of Urology, University Hospitals Leuven, Leuven, Belgium;* [b] *Department of Urology, Erasmus University Medical Centre Cancer Institute Rotterdam, The Netherlands;* [c] *Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK;* [d] *Academic Urology Unit, University of Sheffield, Sheffield UK;* [e] *Department of Urology, Royal Hallamshire Hospital, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK;* [f] *Academic Urology Unit University of Aberdeen, Aberdeen, UK;* [g] *Department of Urology, Aberdeen Royal Infirmary, Aberdeen, UK;* [h] *Department of Urology, Copenhagen University Hospital, Herlev and Gentofte, Copenhagen, Denmark;* [i] *Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark* [j] *Department of Urology, Eberhard Karls University Tübingen, Tübingen, Germany;* [k] *Department of Urology, University Hospital Carl Gustav Carus, Technical University of Dresden, Dresden, Germany*

Table 1 – Summary of current EAU guidelines for prostate cancer PSA testing and early diagnosis [21]

Do not subject men to PSA testing without counselling them on the potential risks and benefits
Offer an individualised risk-adapted strategy for early detection to a well-informed man with life expectancy of at least 10–15 yr
Offer early PSA testing to well-informed men at an elevated risk of having prostate cancer:
1. Men >50 yr of age
2. Men >45 yr of age with a family history of prostate cancer
3. Men of African descent >45 yr of age
4. Men carrying BRCA2 mutations >40 yr of age
Stop early diagnosis of prostate cancer based on life expectancy and PS; men who have life expectancy of <15 yr are unlikely to benefit

EAU = European Association of Urology; PS = performance status; PSA = prostate-specific antigen.

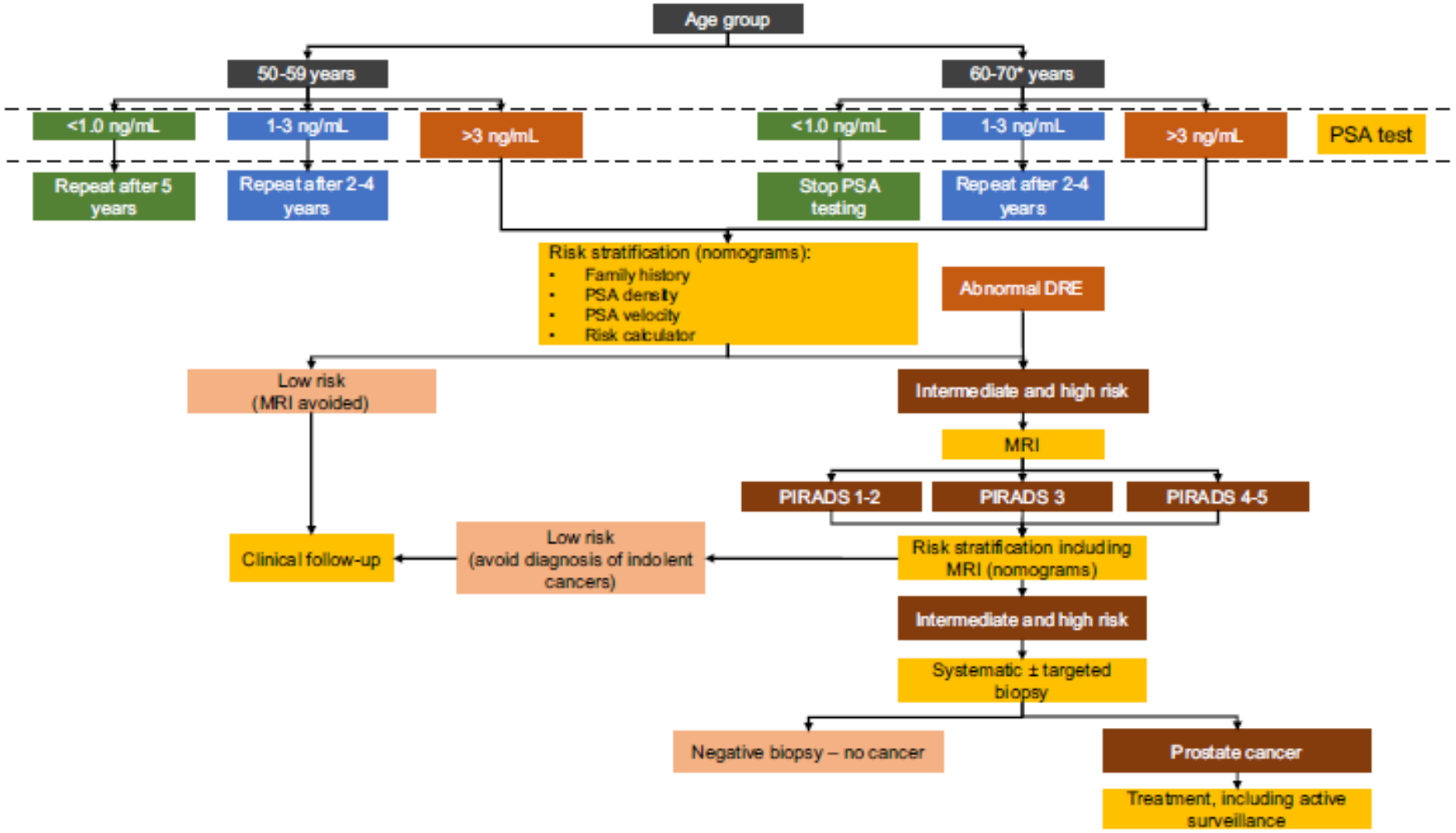


Fig. 4 – Risk-adapted algorithm for the early detection of prostate cancer, adapted based on prostate cancer guidelines published by the EAU [21]. The patient's values and preferences should always be taken into account as part of a shared decision-making process [21].
DRE = digital rectal examination; EAU = European Association of Urology; MRI = magnetic resonance imaging; PIRADS = Prostate Imaging Reporting and Data System; PSA = prostate-specific antigen.
***Healthy men >70 yr without important comorbidities and a life expectancy of >10-15 yr may continue PSA testing.**

The Czech National Cancer Plan 2030

- Prostate cancer is still one of the most common causes of cancer death in men. Current international recommendations tend to suggest that individualised screening may be beneficial for a group of informed men, while grey screening may lead to a lower efficiency and safety of the process. This presents the potential for optimizing investment in this type of care.
- The Ministry of Health, representatives of professional societies and the National Screening Centre have initiated a discussion on a possible pathway to develop a pilot population-based programme for individualised prostate cancer screening.

Evropská unie
Evropský sociální fond
Operační program Zaměstnanost

Národní koordinační centrum programů časného záchytu onemocnění I CZ.03.2.63/0.0/0.0/15_039/0006904
Datová základna realizace screeningových programů CZ.03.2.63/0.0/0.0/15_039/0007216

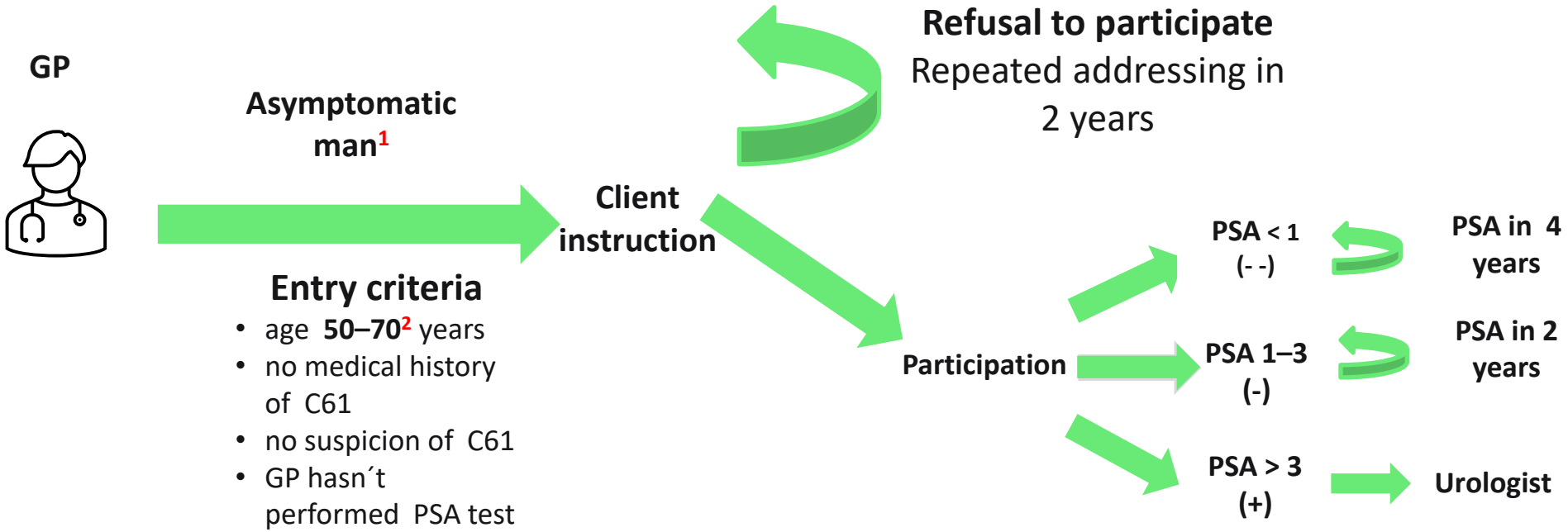
Programme for individualized prostate cancer early detection of in the Czech Republic

Patient flow and indications for MRI

Ústav zdravotnických informací a statistiky České republiky
Institute of Health Information and Statistics of the Czech Republic

MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

Proposal for an early detection scheme for prostate cancer
GENERAL PRACTITIONER (GP)



[1]In case of symptoms, he is referred to a urologist for further diagnosis

[2]Follow the same schedule for men aged >70 yr with good performance status and life expectancy of at least 10–15 yr

Van Poppel H, Hogenhout R, Albers P, van den Bergh RC, Barentsz JO, Roobol MJ. Early detection of prostate cancer in 2020 and beyond: facts and recommendations for the European Union and the European Commission. Screening. 2021 Mar 1;73:56.

Proposal for an early detection scheme for prostate cancer

UROLOGIST

Man in URO dispensary care

Asymptomatic man[1]

Entry criteria

- age **50–70**[2] years
- no medical history of C61
- no suspicion of C61
- URO hasn't performed PSA in the last 2 years

Client instruction

Refusal to participate
Repeated addressing in 2 years

Participation

PSA < 1 (- -) → **PSA in 4 years**

PSA 1–3 (-) → **PSA in 2 years**

PSA > 3 (+) OR **suspected DRE (regardless of PSA level)**

Man referred by GP as part of the screening

Patient referred by GP
PSA > 3

Examinations necessary for MRI decision

- US of the prostate (abdominal or TRUS)
- Repeat total PSA testing
- PSAD
- PSA velocity
- DRE

[1]**In case of symptoms, the diagnostic process is carried out according to professional recommendations**
[2]**Follow the same schedule for men aged >70 yr with good performance status and life expectancy of at least 10–15 yr**

Van Poppel H, Hogenhout R, Albers P, van den Bergh RC, Barentsz JO, Roobol MJ. Early detection of prostate cancer in 2020 and beyond: facts and recommendations for the European Union and the European Commission. Screening. 2021 Mar 1;73:56.

Evropská unie
Evropský sociální fond
Operační program Zaměstnanost

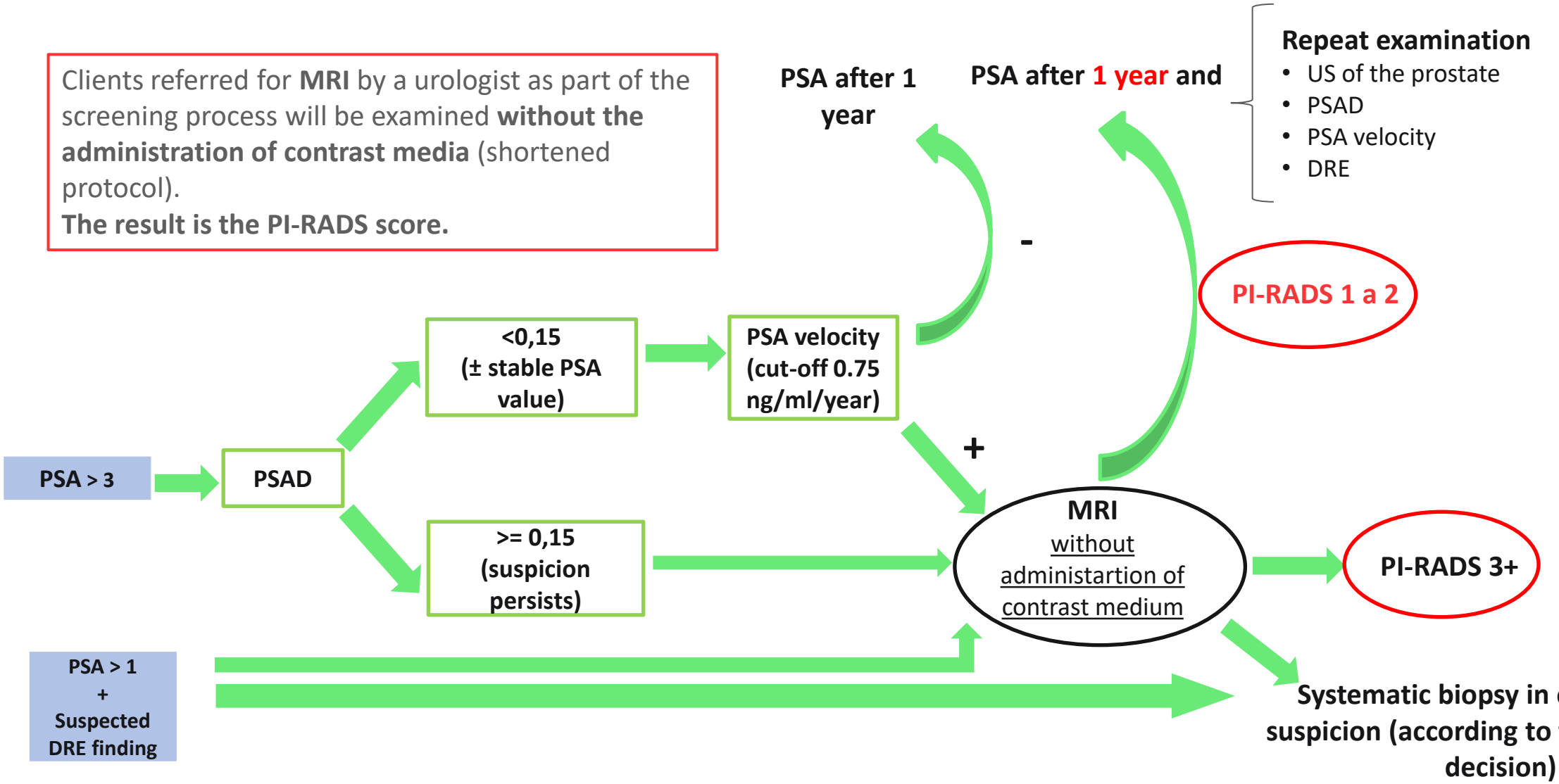
NÁRODNÍ SCREENINGOVÉ CENTRUM

ÚZIS ČR

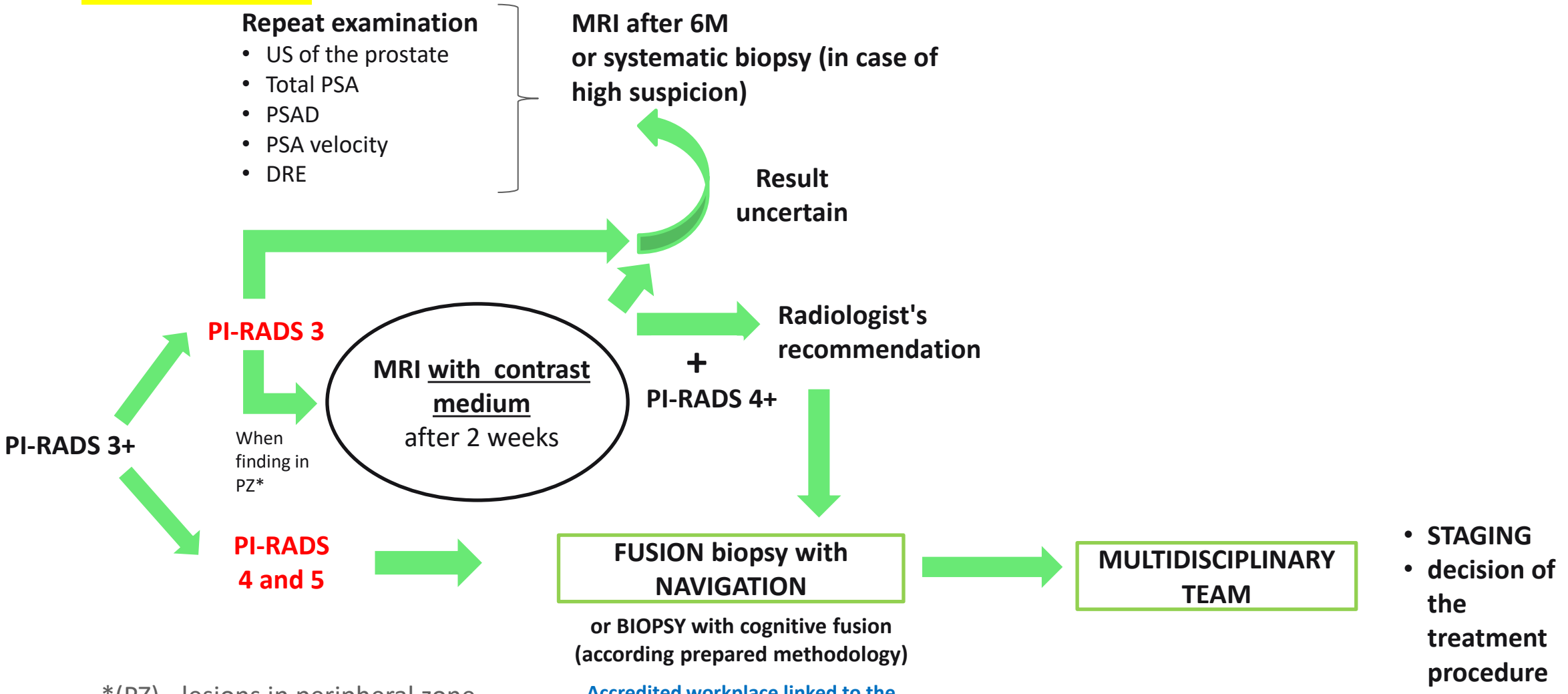
MINISTERSTVO ZDRAVOTNICTVÍ ČESKÉ REPUBLIKY

Diagnostic procedure for PSA > 3 or suspicious DRE

Clients referred for **MRI** by a urologist as part of the screening process will be examined **without the administration of contrast media** (shortened protocol).
The result is the PI-RADS score.



Diagnostic procedure for men with PSA > 3 or suspected DRE and PI-RADS 3+



*(PZ) - lesions in peripheral zone

Patient diagnosed with Ca prostate remains in the care of comprehensive cancer centre