



POPULATION PILOT PROGRAMME FOR PROSTATE CANCER EARLY DETECTION IN THE CZECH REPUBLIC: SITUATION ANALYSIS AND PLANNED DESIGN

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COUNCIL RECOMMENDATION ON STRENGTHENING PREVENTION THROUGH EARLY DETECTION: A NEW EU APPROACH ON CANCER SCREENING REPLACING COUNCIL RECOMMENDATION 2003/878/EC

Prostate cancer

Considering the preliminary evidence and the significant amount of ongoing opportunistic screening, countries should consider a stepwise approach, including piloting and further research, to evaluate the feasibility and effectiveness of the implementation of organised programmes¹⁰ aimed at ensuring appropriate management and quality on the basis of prostate-specific antigen (PSA) testing for men, in combination with additional magnetic resonance imaging (MRI) scanning as a follow-up test.

¹⁰ https://sapea.info/wp-content/uploads/cancer-screening-workshop-report-01.pdf

EU2022.CZ



SCIENTIFIC JUSTIFICATION FOR PROSTATE CANCER SCREENING

- good evidence that prostate cancer screening with PSA testing can reduce deaths from prostate cancer
- overdiagnosis and overtreatment are major harms in prostate cancer screening, due to the high sensitivity of PSA testing
- imposing an upper age limit on screening (possibly around 65–69), and/or a high-quality MRI scan or other accurate additional testing for PSA-positive men, will reduce overdiagnosis and improve the harm-to-benefit ratio
- opportunistic, unorganised PSA testing currently leads to insufficient use in younger men and overdiagnosis in older men
- recent evaluations suggest that there are cost-effective strategies for population-based prostate cancer screening

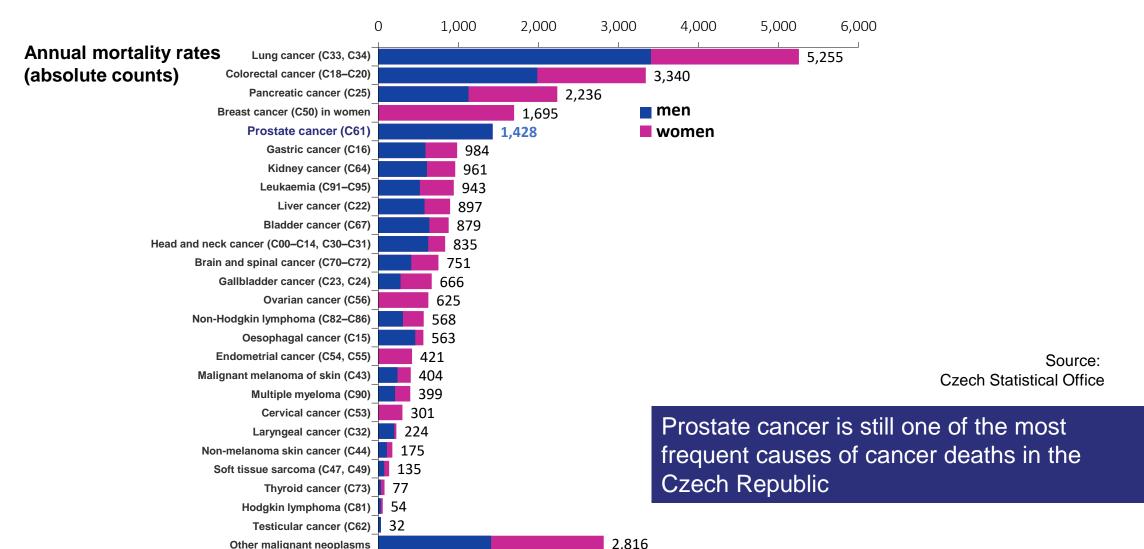
SAPEA, Science Advice for Policy by European Academies. (2022). Improving cancer screening in the European Union. Berlin: SAPEA. https://doi.org/10.26356/cancerscreening



In situ neoplasms, neoplasms of uncertain or unknown behaviour

of other and unspecified sites (D00-D09, D10-D36, D37-D48)

CANCER MORTALITY IN THE CZECH REPUBLIC IN 2017–2021

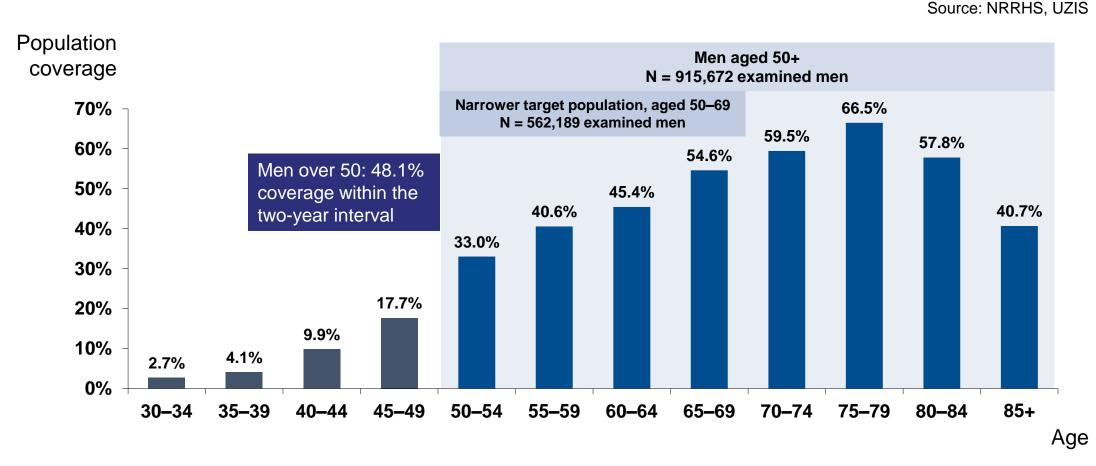


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HALF OF MEN 50+ IN THE CZECH REPUBLIC ALREADY UNDERGO PSA TESTING

PSA examination (93225) (2020–2021, **men over 30**, N = 1,067,199)



The coverage of the target population aged 30 and over in 2021 reaches 29.8% within the two-year interval, increasing substantially from the 50-54 age group and reaching the highest values in the 75-79 age group (66.5%). Coverage of the target population aged 50 and over in 2021 is 48.1% within the two-year interval.



AVERAGE NUMBER OF PSA EXAMINATIONS IN 2019–2021 BY AGE

PSA examination (93225) (2019–2021, men aged over 30) Source: NRRHS, UZIS

Age	2020–2021 2019–202 ²		
30–34	1.15	1.21	
35–39	1.18	1.26	
40–44	1.25	1.39	
45–49	1.31	1.49	
50-54	1.38	1.61	
55–59	1.55	1.87	
60–64	1.75	2.18	
65–69	1.96	2.50	
70–74	2.13	2.81	
75–79	2.25	3.00	
80–84	2.21	2.92	
85+	2.06	2.64	
Total 30+	1.79	2.23	
Total 50+	1.88	2.38	

Average number in individuals undergoing PSA



PREPARATORY STEPS FOR THE NEW PROSTATE CANCER EARLY DETECTION PROGRAMME IN THE CZECH REPUBLIC

Preparatory work started in 2022

- Multi-stakeholder engagement: roundtable (2022) and the formal
 Committee for Preparation of the Prostate Cancer Early Detection Programme (2023)
- Small scale pilot project concluded
 - Process characteristics in cancer survivors and in general population
- Analysis of situation and potential impact of the organised programme
- Preparation of strategy and implementation guidelines for population pilot project





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National health Planned Small scale **Implementatio** information **Projected costs** screening pilot project's and monitorin system analysis: and outcomes strategy prostate cancer result guidelines formulated burden and care ment evidence supports potential opscaling of targeted prostate concer detection to the general mole population, e-pilot project provided obaranteristics of the screening process in the Caseh population, which will be used to inform decisions about otential universal large scale pilot programme in the Czech Republic

process in cancer survivors and in general population. Marcela Koudelkowalijush o tate cancer is still one of the most frequent causes of cancer deaths in Caschia A total of 304 men were examined in arm.A:

81 patents (18.8 %) had a real ever of PSA assenting to the project. nd the Working Group under the expert guarantee of Positive result of the product bippy was confirmed by a prologist. Positive result of the product bippy was confirmed in 5 patients, reasons core accreting to source wide 1 (2) 4 (2) seed 2 (2) 4 (4) once 4 (4) 4 (4). centrol arm B included 1,105 men with a mean age of 60 years history). Based on the PSA result, the physician desided on father lealing Work men were advised to have a follow-up after 2 years (31.7 %) or 4 wars (13.5 %). har aim was to estimate characteristics of the prostate cancer eat-



PROPOSED CZECH POPULATION PILOT PROGRAMME FOR EARLY DETECTION OF PROSTATE CANCER: PROPOSED METHODOLOGY

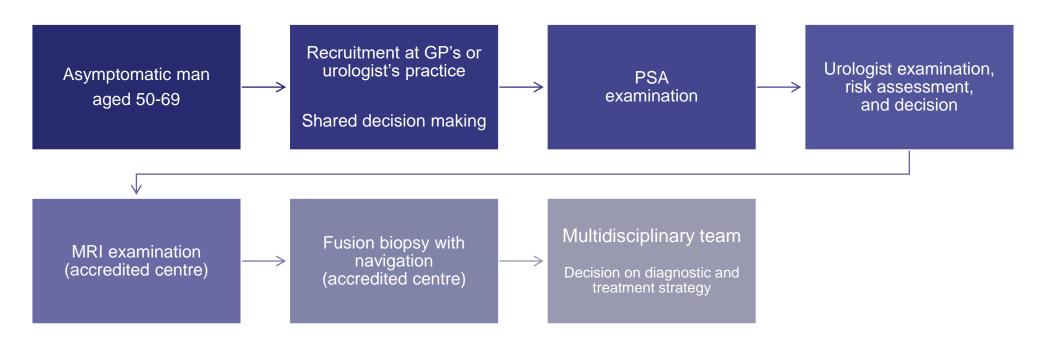
- Potential launch of the programme
 - **2024**
- Target population
 - men aged 50-69 years (+364 days) with no history of prostate cancer and no suspicion of prostate cancer
- Screening test
 - PSA examination
- Governance and coordination
 - Committee for Preparation of the Prostate Cancer Early Detection Programme
- Monitoring and evaluation
 - National Screening Centre, Institute of Health Information and Statistics of the Czech Republic



PROPOSED CZECH POPULATION PILOT PROGRAMME FOR EARLY DETECTION OF PROSTATE CANCER: SIMPLIFIED PATIENT PATHWAY

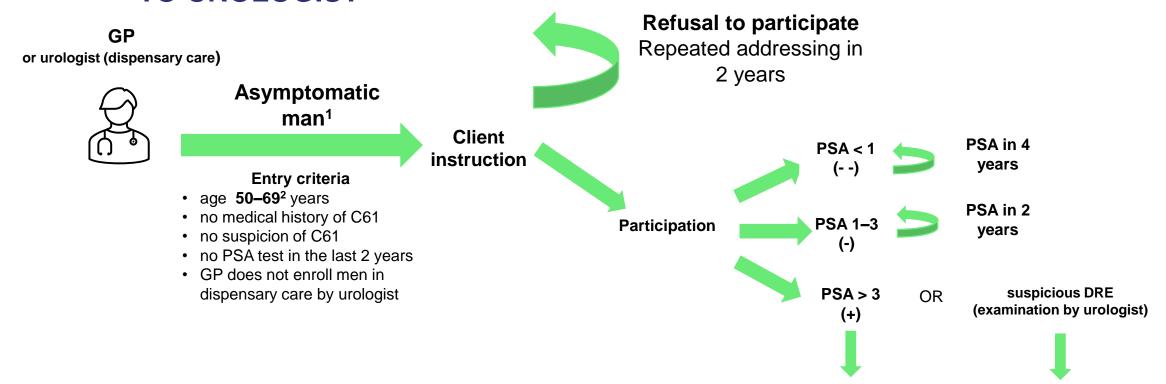
Process

- GPs or urologists offers the programme, educate the patients, take sample for PSA examination
- urologists perform complex examination and potentially refer the patient for MRI examination
- MRI is provided only at radiological departments accredited by the Ministry of Health
- fusion biopsy is provided only at urological departments accredited by the Ministry of Health





PROPOSED CZECH POPULATION PILOT PROGRAMME FOR EARLY DETECTION OF PROSTATE CANCER: SCREENING TEST AND REFERRAL TO UROLOGIST



¹In case of symptoms, the diagnostic process is carried out according to professional recommendations

²Follow 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.

Urologist – examination and risk assessment

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



ESTIMATED PROSTATE CANCER DETECTION COSTS: CURRENT SITUATION (ANNUAL COSTS, 2021)

Estimation methodology (real-world practice according to reimbursement data, 2021)

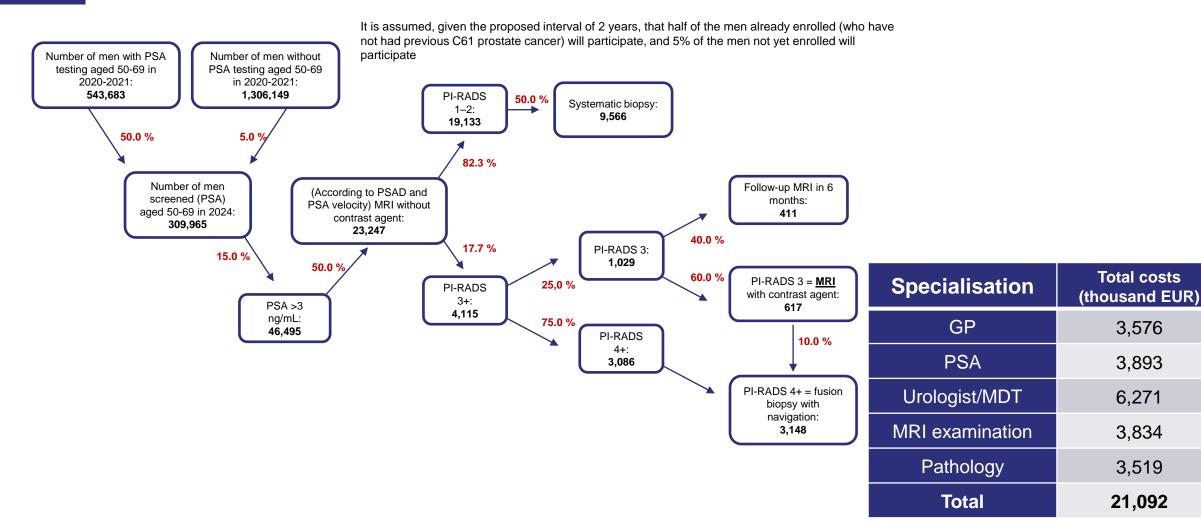
- PSA test, prostate biopsy: all procedures
- Examination by a urologist, ultrasound, multidisciplinary team: procedures in men with PSA
- MRI examinations: procedures indicated by urologist or associated examinations
- Pathology examinations: following biopsy procedures by a urologists
- Men with previous prostate cancer diagnosis not included

Key results

Examination	Number of examinations	Annual costs (thousand EUR)	Number of examinations	Annual costs (thousand EUR)	Number of examinations	Annual costs (thousand EUR)
	Men aged 50–69 years		Men aged 70+ years		Men aged under 50 years	
PSA tests	479,215	4,445	319,144	2,960	116,126	1,077
•••						
Total annual costs (thousand EUR)		17,314		13,746		2,957



MODELLED PROCESS AND ANNUAL COSTS FOR THE ORGANISED PROGRAMME (EXAMPLE OF BASELINE SCENARIO)



The results represent the indicative costs obtained through the mathematical model. The overall analytical output also includes a detailed breakdown of costs by individual health interventions and a sensitivity analysis of the input assumptions.



ESTIMATED COSTS COMPARISON OF CURRENT SITUATION AND PROPOSED PROGRAMME: SUMMARY OF INDICATIVE RESULTS

- Currently, in the group of older men, contrary to the recommendations, there is a very intensive PSA testing. The cost to the health system for PSA testing and related care (including possible diagnosis and dispensing of prostate disease) can be estimated at approximately 17 million EUR for men aged 50-69 years and almost 14 million EUR for older men.
- Under the baseline scenario, the modelled cost of the proposed programme algorithm is 21 million (annual cost in the 50-69 age group).
- The results represent the indicative costs obtained through the mathematical model. The overall analytical output also includes a detailed breakdown of costs by individual health interventions and a sensitivity analysis of the input assumptions.



PROSTATE CANCER SCREENING IS PROPOSED AS A 5YEAR POPULATION PILOT PROGRAMME

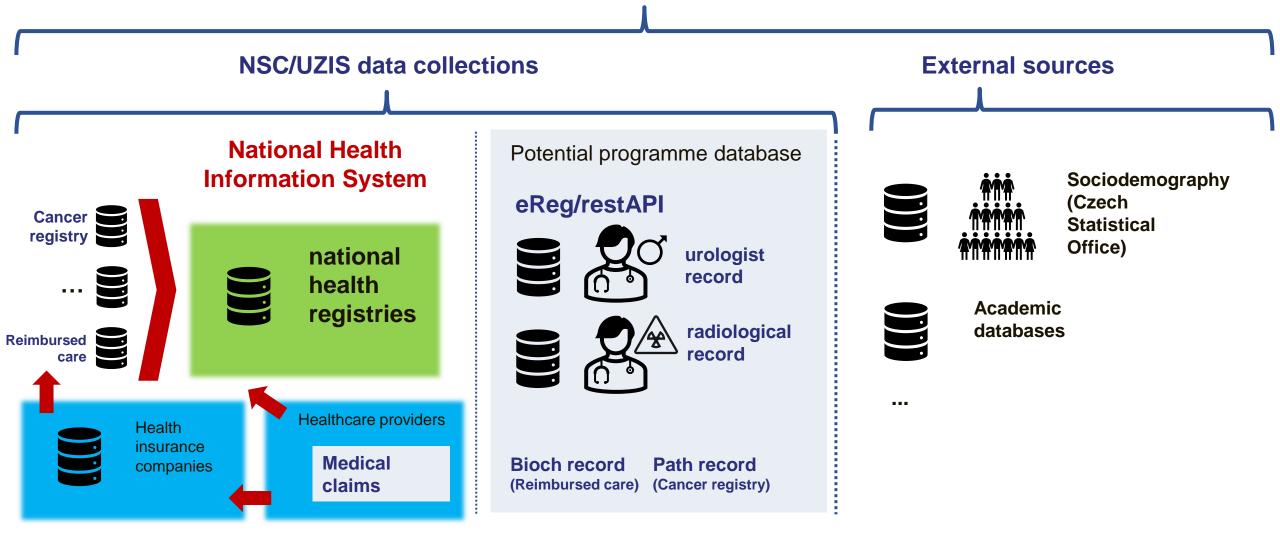
Why is it still important to learn? (i.e. embed research into the pilot)

- To gain experience with feasibility and acceptability
- To identify the characteristics of the screening process in the Czech context (completing the HTA assessment)
 - Inclusion of new men vs. elimination of non-programme screening
 - Positivity, negative/positive predictive value, detection rate
 - Participation rate in complementary testing and therapy (compliance)
 - Determination of economic characteristics (cost per disease captured, cost-effectiveness, budget impact)
- To collect data for possible further optimisation of the screening process
 - Targeting or stratification of screening



COMPREHENSIVE INFORMATION SYSTEM TO CONTROL THE PROGRAMME

Quality assurance information system





PROPOSED SET OF KEY PERFORMANCE INDICATORS

- 1. Percentage of men agreeing to be included in the programme
- 2. Percentage of men with an abnormal PSA result
- 3. Participation rate of men with an abnormal result in urological examination
- 4. Participation rate of men in bpMRI examination
- 5. Proportion of indeterminate MRI results (PI-RADS 3)
- 6. Participation rate of men with indeterminate MRI results (PI-RADS 3) in repeat MRI examinations
- 7. Proportion of men with a positive MRI scan undergoing fusion biopsy
- 8. Proportion of men undergoing systematic biopsy, by MRI result
- 9. Proportion of patients with a positive biopsy result undergoing multidisciplinary assessment at the highly specialized cancer/urooncology centre
- 10. Prostate cancer detection rate, by Gleason score (especially 3+4+, 4+3+)
- Time intervals between events
- 12. Completeness of the data record



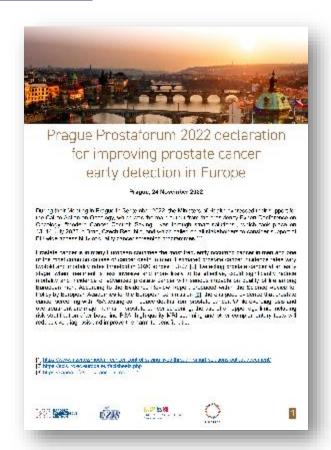


CONCLUSIONS

- Prostate cancer is still a serious health problem in the Czech Republic, being the third most frequent cancer cause of death.
- Organised prostate cancer screening is potentially effective tool to decrease mortality from prostate cancer
- Current highly prevalent opportunistic screening is likely inefficient, and the need for organisation of the care is therefore warranted.
- The consensus guidelines for an organised programme are currently being finalised and approved, with expected start of the population pilot project from 2024.



CONFERENCE PROSTAFORUM 2022, PRAGUE, 24 NOVEMBER 2022







https://prostaforum.uzis.cz/en/ prague-prostaforum-declaration/

EUROPEAN UROLOGY OPEN SCIENCE 53 (2023) 106-108

available at www.sciencedirect.com journal homepage: www.eu-openscience.europeanurology.com





Brief Correspondence

How to follow the new EU Council recommendation and improve prostate cancer early detection: the Prostaforum 2022 declaration

Ondřej Májek ^{a,b,*}, Marek Babjuk ^c, Monique J. Roobol ^d, Ola Bratt ^{e,f}, Hendrik Van Poppel ^{g,h}, Roman Zachovalⁱ, Jiří Ferda^j, Marcela Koudelková^{a,b}, Ondřej Ngo^{a,b}, Jakub Gregor^{a,b}, Sarah Collen^g, Karel Hejduk^{a,b}, Ladislav Dušek^{a,b}, Vlastimil Válek^{b,k}

Please consider endorsing the Prague declaration



THANK YOU FOR YOUR ATTENTION!

THANKS TO NUMEROUS COLLABORATORS AND STAKEHOLDERS



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