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SMART EARLY DETECTION OF PROSTATE CANCER

Prostate Cancer Screening: first results from the PRAISE-U project

Prof.Dr. M.J. Roobol, Erasmus University Rotterdam, NL

Erasmus MC

URO ART BASEL

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Coordinator: EAU
Consortium: 20 beneficiaries and 5 associated partners
Funding: €9,849,062.50 under EU4Health
Start date: April 1, 2023
Duration: 36 months

www.praise-u.eu

Funded by the European Union

Sister projects: SOLACE (Lung cancer) and TOGAS (gastric cancer)

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Consortium of 25 institutions from 12 Member States

BENEFICIARIES

Erasmus MC
eau
UMC Utrecht
midt regionmidtjylland
ERSPC European Randomized Study of Screening for Prostate Cancer
ÚZIS
REGION SKÅNE
EESTI UROLOOGIDE SELTS 1962
NACIONALINIS VĖŽIO INSTITUTAS NCI 90 METŲ
european cancer ORGANISATION
DCOPiH
UNIVERSITEIT GENT
XUNTA DE GALICIA CONSELLERÍA DE SANIDADE
althaia
REGION VÄSTRA GÖTALAND
HSE
UCD DUBLIN
NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO PAŃSTWOWY INSTYTUT BADAWCZY
MOVEMBER®
Wonca World family doctors. Caring for people. EUROPE

ASSOCIATED PARTNERS

International Agency for Research on Cancer
World Health Organization
EUROPA UOMO The Voice of Men with Prostate Cancer in Europe
ESUR
ČUS
Karolinska Institutet
KAROLINSKA UNIVERSITETSSJUKHUSET
Karolinska Comprehensive Cancer Center

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PRAISE-U Mission

To **raise awareness** of PCa and its implications

To get insights and **assess needs** in EU member states **to design** a diagnostic strategy and algorithm for Prostate Cancer Screening in the EU member states that is **cost-effective**

The algorithm will be refined on the basis of information coming from **5 PRAISE-U Pilot studies** and through knowledge sharing with ongoing and to be started initiatives (EUCanScreen)

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International Agency for Research on Cancer

World Health Organization

Year 1

WP2: Knowledge hub:

- Living state-of-play document
- Needs assessment report
- Digital Platform
- Indicators of screening effectiveness

WP3: Development of model for screening:

- Capacity assessment
- Site-specific protocols
- Quality assurance and knowledge tools

Year 2

eau

WP4: Implementation pilots

Year 3

UMC Utrecht

WP5: Evaluation and Sustainability

eau

WP1 &6: coordination and communication

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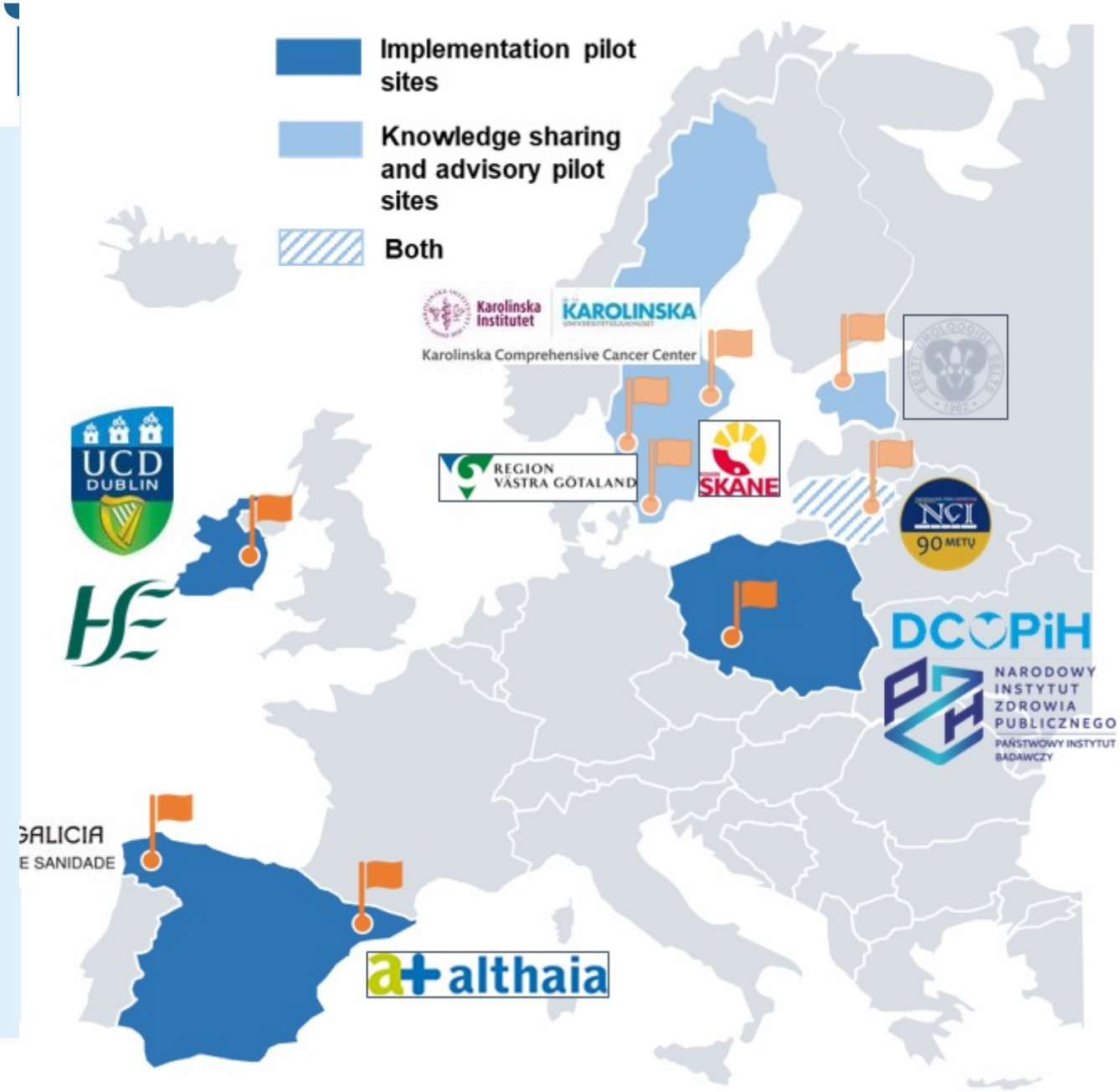

Knowledge sharing:

OPT Sweden
Estonia (Estonian Urological Association)

Knowledge sharing and starting new pilot

Lithuania (National cancer Institute, Narodowy Inst)

Implementation of new pilot

Ireland (Univ College Dublin, Health Services Exec)
Spain (Conselleria de Sanidade de Galicia and Funadio Althaia)
Poland (DCOPiH: center for Oncology, pulmonology, hematology)

More counties will join sharing their data and knowledge

-> PRAISE-U knowledge platform.

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WP2: Knowledge hub:

- Living state-of-play document
- Needs assessment report
- Digital Platform
- Indicators of screening effectiveness

State-of-Play of PCa screening in the EU members states

- PRAISE-U: RCT towards program
- Policy SR: *"health policy for PCa early detection in the EU and the impact of opportunistic screening: PRAISE-U"*
- State of Play SR: *"The state of play on PCa early detection in the EU: a systematic review of contemporary literature"*
- Cost-effectiveness SR: *"Systematic review on the cost-effectiveness of PCa screening in Europe"*

Deadline Month 8 (December 2023)

Journal of Personalized Medicine
MDPI

Article

Navigating through the Controversies and Emerging Paradigms in Early Detection of Prostate Cancer: Bridging the Gap from Classic RCTs to Modern Population-Based Pilot Programs

Juan Gómez Rivas [1,*], Renée C. A. Leenen [2], Lionne D. F. Venderbos [2], Jozien Helleman [2], Irene de la Parra [1], Vera Vasilyeva [3,4], Jesús Moreno-Sierra [1], Partha Basu [5], Arunah Chandran [5], Roderick C. N. van den Bergh [2,6], Sarah Collen [3,4], Hein Van Poppel [4,7], Monique J. Roobol [2], Katharina Beyer [2] and on behalf of the PRAISE-U Consortium [†]

J. Pers. Med. **2023**, *13*, 1677. https://doi.org/10.3390/jpm13121677

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Journal of Personalized Medicine
MDPI

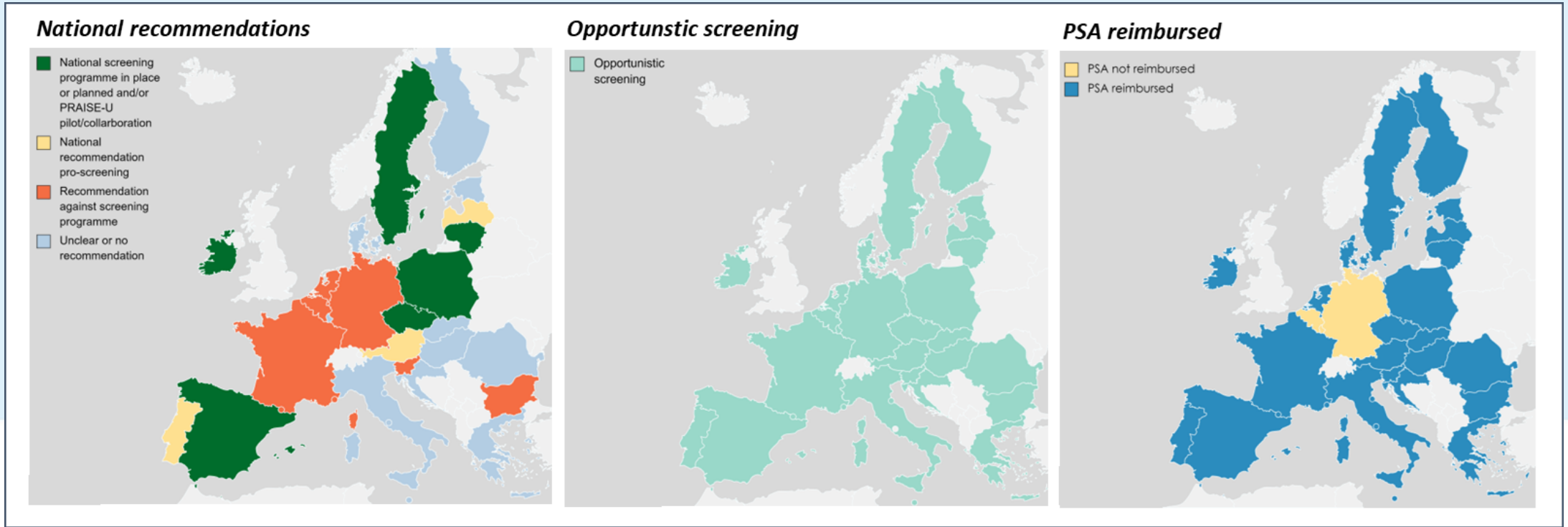
J. Pers. Med. **2024**, *14*, x.

Systematic Review

Health Policy for Prostate Cancer Early Detection In the European Union and the Impact of Opportunistic Screening: PRAISE-U Consortium

Katharina Beyer [1,*], Renée Leenen [1], Lionne D. F. Venderbos [1], Jozien Helleman [1], Frederique Denijs [1], Wichor Bramer [2], Vera Vasilyeva [3], Erik Briers [4], Juan Gomez Rivas [5], Renata Chloupkova [6,7], Ondrej Majek [6,7], Lieven Annemans [8], Pieter Vynckier [8], Partha Basu [9], Arunah Chandran [9], Roderick van den Bergh [1], Sarah Collen [3], Hendrik van Poppel [3], Monique J. Roobol [1] and PRAISE-U Consortium

- Review the policy, medical guideline recommendations, and the current level of opportunistic screening presented in the scientific literature on prostate cancer early detection from 2016 to 2023 in European Union member states.
- An extensive literature search was performed on 1 June 2023 in a large number of databases, 17 articles were ultimately identified as eligible for inclusion.
- The included articles **revealed significant variations towards PSA-based early detection policies for prostate cancer in nine European countries.**



- Despite official recommendations, **opportunistic screening was prevalent across all nine countries** regardless of recommendations for or against PSA-based early detection.

- **The current early detection policies are not fit for purpose**. High levels of opportunistic screening and overdiagnosis persist, prompting policy recommendations for standardised guidelines, informed decision making, and increased awareness to improve efficiency and effectiveness in early detection.

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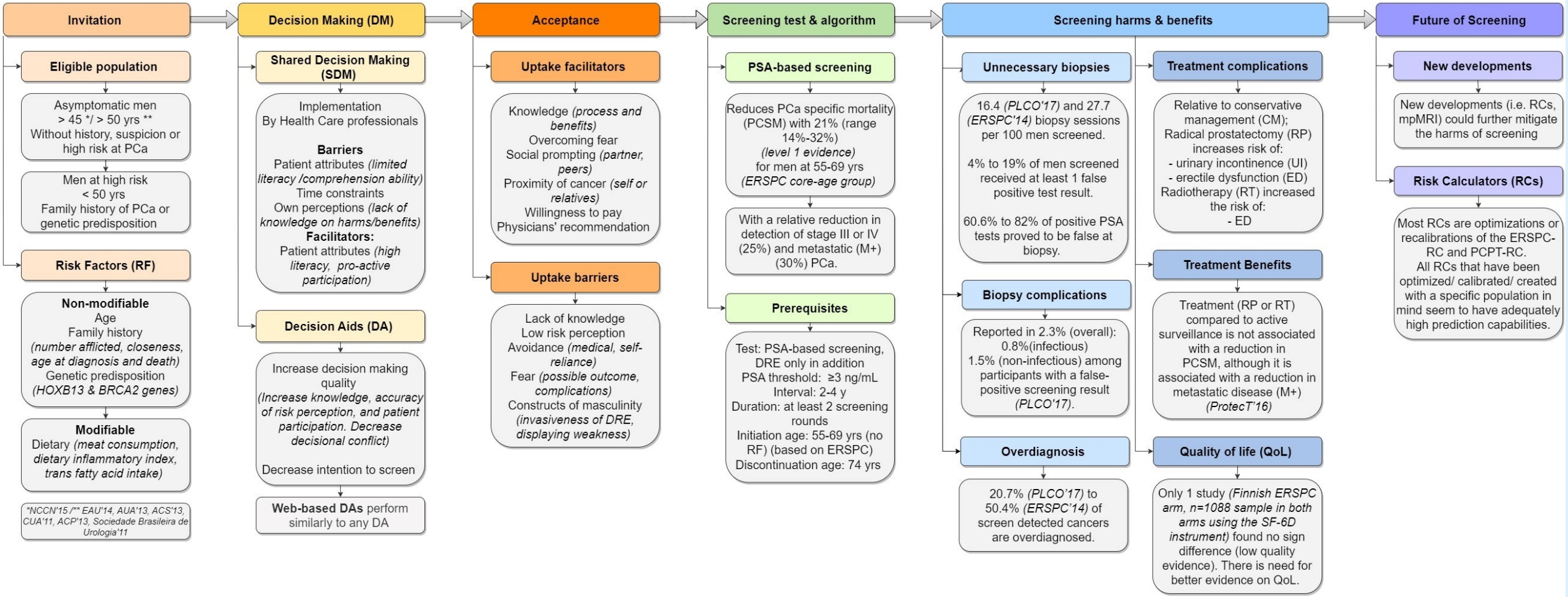
- *"The state of play on PCa early detection in the EU: a systematic review of contemporary literature"*

Figure 1. Summary table of the identified themes, sub-themes and main findings



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A total of 19 studies described the health economic evaluation of prostate cancer screening and were included in the analysis.

Of the included studies focusing on **initially healthy subjects**, and comparing **screening modalities with no screening**, ICERs varied from €11,091/QALY gained to €372,948/QALY, with a median of €37,398/QALY.

Overall, **risk based PCa screening seemed to be more cost effective** compared to the overall result (median ICER: €24,663/QALY).

Within all these studies, a remarkable difference was found in ICERs based on the age (range) of the target group. **Higher ICERs were found with higher age, and thus screening appears to be less cost-effective for higher age groups**

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Needs Assessment: BEST tool

Following the guidance of the EU-TOPIA EAST 'Barriers to Effective Screening Tool (BEST)', we developed a survey. The survey is tailored specifically to understand (potential) PCa screening programmes' barriers. To be filled in by all relevant stakeholders!!!

Part 1

- Your country and region?
- Your job role?
- Is there an organized population-based screening program for PCa in operation or planned in your country?

Part 2

- Importance of these barriers to the overall success of an already established or future PCa screening program in your country?
  - e.g., Political support, Knowledge? …other?

The results of this survey will help us identify and prioritize the barriers to be addressed, evaluate the effectiveness of current resource allocation, and inform the development and improvement of current and future prostate cancer screening programs.

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Needs Assessment: BEST tool

Physical Flyer
(entails QR code to the newsletter)

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The Barriers to Effective Screening Tools Survey

This survey is a modified version of one used in the EU-TOPIA project (TOwards imProved screening for breast, cervical, and colorectal cancer In All of EUrope), tailored specifically for assessing prostate cancer screening programs. Its primary goal is to enable clinicians, patients, screening organizers, researchers, and policymakers to conduct a self-assessment of their current or future prostate cancer screening programs. By identifying the most significant barriers to screening, we can prioritize them, consider feasibility, and explore potential solutions to overcome these obstacles.

Your participation and dissemination will contribute to the development of early detection protocols for prostate cancer.

Your Role

We need your help disseminating this survey. In order for this survey to be as effective as possible we need to reach as many respondents as possible. This QR code links to an email describing and linking to the survey.

We request that you forward that email to your network. Anyone who is a clinician, patient, screening organizer, researcher, or policy maker is eligible.

Simply:

- Scan the QR code
- Click "share"
- And forward to your network!

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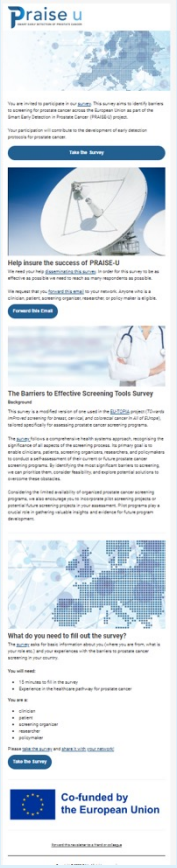
Newsletter to access the survey and to spread the word and share with your network



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Help insure the success of PRAISE-U

The Barriers to Effective Screening Tools Survey

What do you need to fill out the survey?

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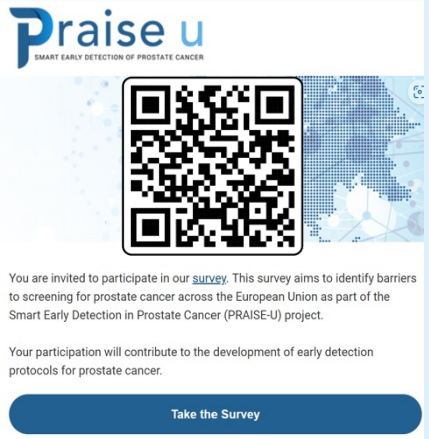
Needs Assessment: BEST tool

How to fill in the BEST tool?

Scan the QR code (or click on the link) → Enter the password: praise_U → Chose language and Click → Sign informed consent → Take the survey and share



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In PRAISE-U, there are 56 unique countries, with a total of 413 responses

EU-27

Number of responses is 301 from 28 countries

Other, N = 14[1]	Patient representing a patient organisation, N = 26[1]	Policy stakeholders, N = 18[1]	Primary care, N = 56[1]	Researcher, N = 19[1]	Urologist, N = 165[1]

PRAISE-U calls for cooperation for prostate cancer screening

The National Societies Meeting brings PRAISE-U insights from around the world

Fri, 14 Jul 2023 • Kevin P. McBride

Prostate Cancer | PRAISE U | Policy | EAU Policy Office

Since the kick-off of PRAISE-U in Brussels this April, the consortium has been hard at work building the foundation of this ambitious EU-wide prostate cancer early detection project. While PRAISE-U is a three-year project, these early steps require an influx of data and experiences from urological colleagues around the world. Thus, Praise-U representatives attended the National Societies Meeting in Noordwijk, the Netherlands, to present the project and gather information for the prostate cancer knowledge hub.

Characteristic	N = 301[1]
Which country are you representing?	
Italy	46 (15%)
Spain	28 (9.3%)
Netherlands	26 (8.6%)
Germany	19 (6.3%)
Hungary	14 (4.7%)
Belgium	13 (4.3%)
Estonia	12 (4.0%)
Portugal	12 (4.0%)
Bulgaria	11 (3.7%)
France	11 (3.7%)
Denmark	10 (3.3%)
Lithuania	10 (3.3%)
Finland	9 (3.0%)
Czechia	8 (2.7%)
Ukraine	8 (2.7%)
Ireland	7 (2.3%)
Slovakia	7 (2.3%)
Cyprus	6 (2.0%)
Greece	6 (2.0%)
Romania	6 (2.0%)
Sweden	6 (2.0%)
Poland	5 (1.7%)
Slovenia	5 (1.7%)
Austria	4 (1.3%)
Croatia	4 (1.3%)
Latvia	3 (1.0%)
Luxembourg	3 (1.0%)
Malta	2 (0.7%)

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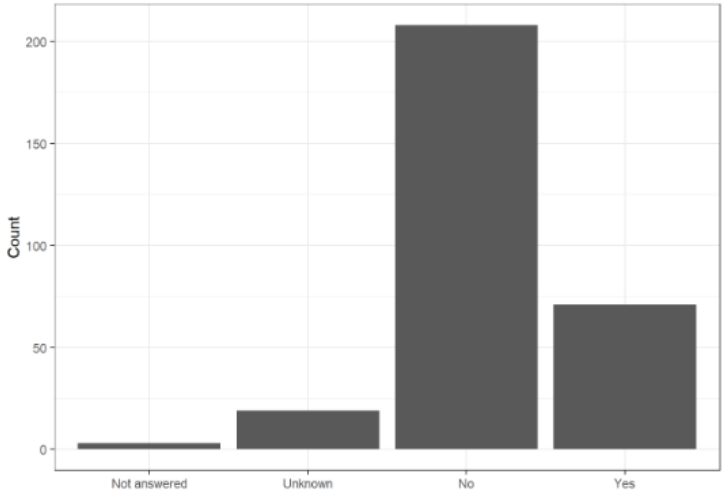
BEST Survey

1.1 Is there an organised, population-based screening program for prostate cancer currently in operation or planned for the future (i.e. between now and June 2024) in your country?

Characteristic	N = 301[1]
Is there an organised, population-based screening program for prostate cancer currently in operation or planned for the future (i.e. between now and June 2024) in your country?	
No	208 (69%)
Not answered	3 (1.0%)
Unknown	19 (6.3%)
Yes	71 (24%)

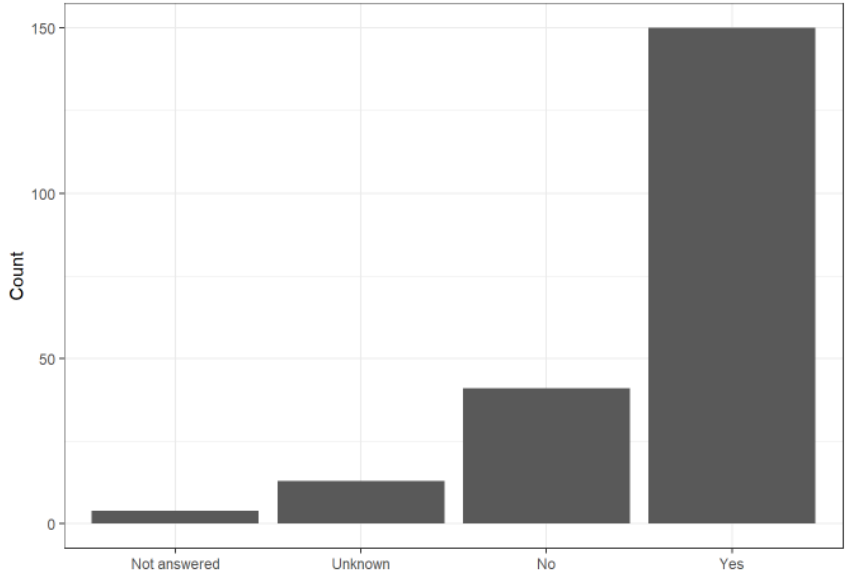
[1] n (%)



2.2 Would you support an organised population-based screening programme in your country?

Characteristic	N = 208[1]
Would you support an organised population-based screening programme in your country?	
Not answered	4 (1.9%)
Unknown	13 (6.3%)
No	41 (20%)
Yes	150 (72%)

[1] n (%)



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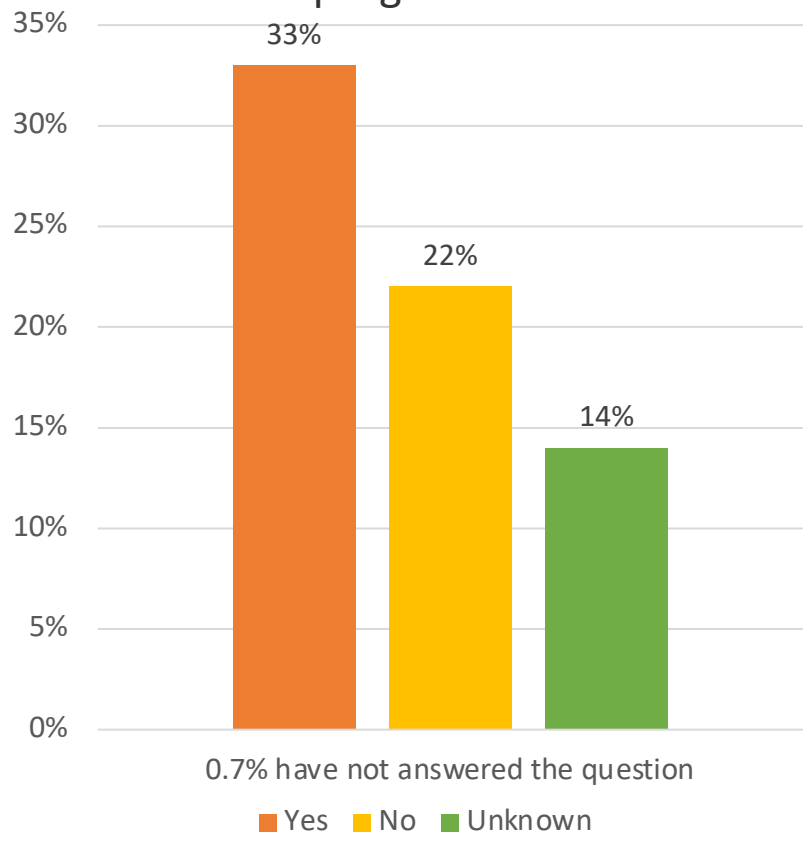
Does the European Commission recommendation influence your opinion towards organised population-based screening programmes?



Conclusions

Most respondents reported the absence of a population-based screening program in their respective countries. Instead, they have noted the presence of opportunistic screening and expressed their support for the establishment of a population-based screening program. Nevertheless, in line with PRAISE-U, the successful implementation of such a program requires political support, public awareness and the development of protocols, processes, and legal frameworks, while generating data.

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- **Pilots will start in April 2024**
- Currently protocols are finalized
- **K**ey **P**erformance **I**ndicators almost complete (consensus with stakeholders)
- Study database is defined and in development
- Pilots will implement **a risk based strategy** with a **nationally tailored** character

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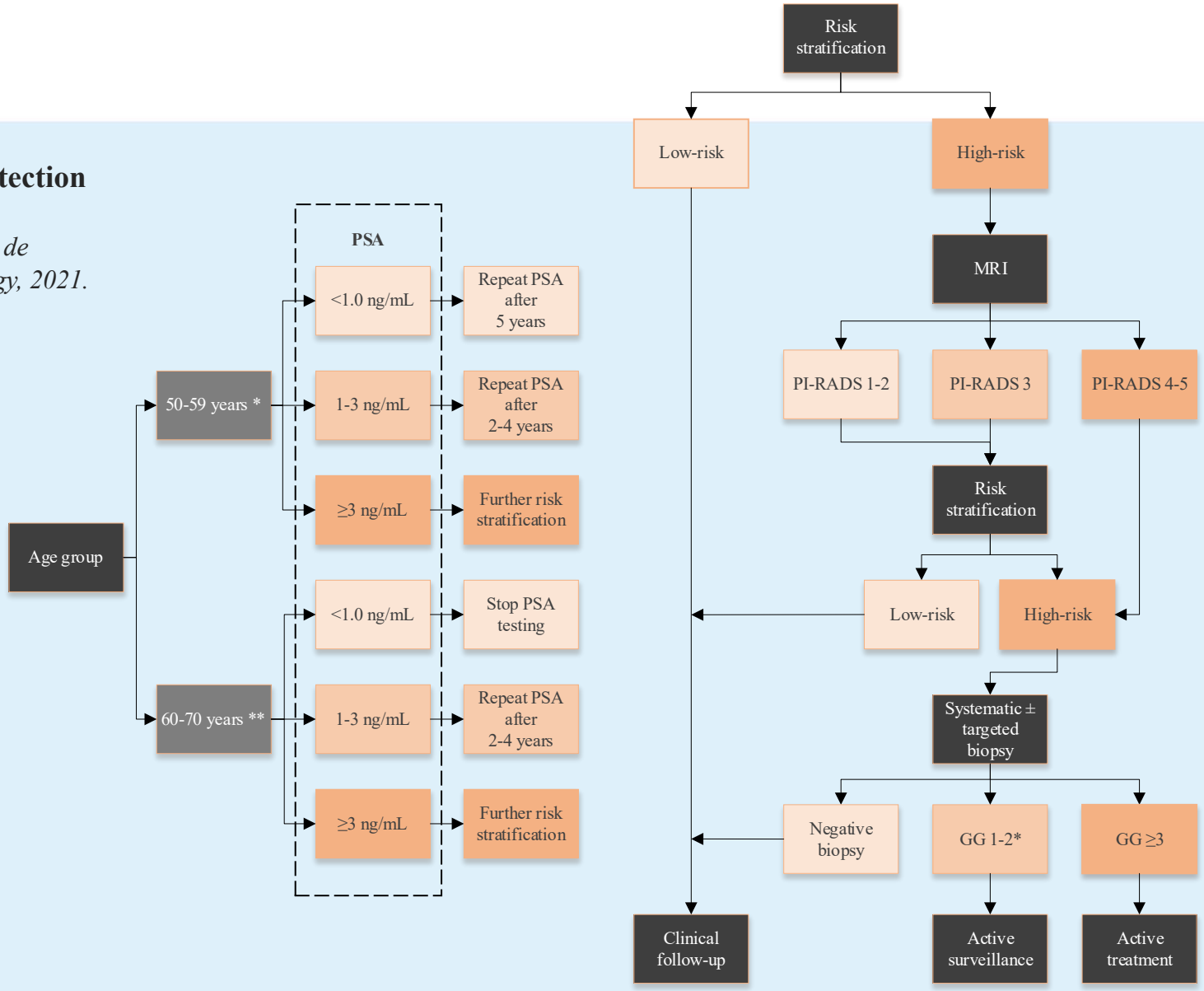
A European Model for an Organised Risk-stratified Early detection Programme for Prostate Cancer

Hendrik Van Poppel†, Renée Hogenhout†, Peter Albers, Roderick C.N. van de Bergh, Jelle O. Barentsz‡, Monique J. Roobol‡. *European Urology Oncology, 2021.*



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	Lithuania	Galicia	Manresa	Poland	Ireland
Invitation	10,000	12,000	5,620	35,000 **Mobile units, rural**	8,000
PSA	Lab primary care	Lab in hospital	Lab primary care	Lab in screening centre	**Home-based testing**
DRE	yes	yes	**No**	yes	yes
Volume	**suprapubic**	**suprapubic**	**suprapubic**	TRUS	**Based on DRE**/MRI
Risk calculator ERSPC Rotterdam	yes	yes	**PSA-Density**	yes	Irish nomogram
MRI	mpMRI	mpMRI	**bpMRI**	**bpMRI**	mpMRI
Biopsy	TRUS/MRI fusion	TRUS guided fusion	Cognitive fusion	TRUS guided fusion	TRUS guided/cognitive fusion

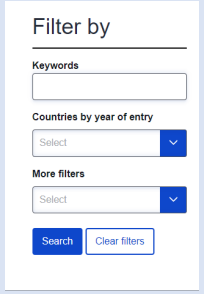
Summarise all our knowledge in fact sheets

And bring them to al relevant stakeholders !!! -> Knowledge HUB on prostate cancer screening: **uroweb.org/praise-u**

Fact Sheets: Screening

Welcome to the Fact Sheets website. The Fact Sheets aim to gather information on the health care system, national cancer control plan, current practice, guideline recommendation and future outlook across the 27 EU Member States on Prostate Cancer early detection. They have been created based on a grey-literature review and focus groups with national representatives from the respective Member State.

Country profiles (27)



Slovevenia

Spanish example

Sweden

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Screening Fact Sheet

Spain

FAST FACTS

Life expectancy
84 years (2019)[1]

Reimbursement
PSA tests are free

Testing location
GPs

Health System Background

The national health system – Sistema Nacional de Salud (SNS) – is based on universal coverage and is mainly funded from taxes. While national planning and regulation remain the responsibility of the Ministry of Health, health competences and primary jurisdiction over operational planning at the regional level, resource allocation, purchasing and provision are devolved to the 17 regional health authorities.

Local Screening State of Play

National Cancer Plan

In March 2021, Spain updated its 10-year National Plan for Cancer, aiming to improve the quality of care received by cancer patients and the support provided to their families.

Who organizes screening programmes?

Each of Spain's 17 autonomous regions organizes its screening. There is no national/regional screening program.

What is happening in practice?

The screening is opportunistic. GPs use their own criteria to decide whether to screen for PSA or not. Most people over 50 probably have PSA done (not supported by data)[2]. In 2015, GPs in Catalonia region requested PSA on 15.2% of males[3]. Officially, risk calculators are not supported.

RECOMMENDATIONS

HTA/Gov.

No screening program is recommended, neither at the individual or population level (2006).

The benefit-risk ratio of prostate cancer screening is not established. There is no evidence that cancers diagnosed from screening programs have better outcomes than cancers diagnosed from clinical symptoms.

On the contrary, the risks associated with early detection and treatment are considered to be significant (from 2021).

National Urology Guidelines

The Spanish Urological Society does not recommend PSA testing before the age of 50, except in cases where there is a family history. After the age of 50, however, it is strongly recommended.

The recommendation is that 'patients' should be well informed when deciding whether to undergo the test i.e., PSA test, men aged 50 and above at intervals of 2-4 years. Prostate examination through Digital Rectal Examination (DRE) is not recommended. Screening should be discontinued at 69 years or earlier, particularly if there is comorbidity that limits life expectancy to less than 10 years. It may also be halted at 65 years if PSA levels are below 1.0 ng/ml. In cases where PSA levels exceed 7 ng/ml, immediate referral to a specialist is recommended without further testing. For PSA levels between 4-7 ng/ml, it is suggested to reevaluate after a few weeks.

OUTLOOK

The GP perspective is that it is likely that the national strategy will change if new evidence is offered.

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[1] https://health.ec.europa.eu/system/files/2021-12/2021_chp_es_english.pdf

[2] Salinas M, López-Garrigós M, Miralles F, Chinchilla V, Ortuño M, Aguado C, Marcaida G, Guaita M, Carratala A, Díaz J, Yago M. Evaluation of PSA testing by general practitioners: regional study in the autonomic Community of Valencia. Archivos Espanoles de Urologia. 2011 Jun 1;64(5):435-40.

[2] Giménez N, Filella X, Gavagnach M, Allué JA, Pedrazas D, Ferrer F. Prostate cancer screening using prostate-specific antigen: The views of general and laboratory physicians. Semergen. 2018 Mar 21;44(6):409-19.

[3] Junquera JM, Ciutat LF, Comalat AF, Rosell LC. Analysis of recommendations against prostate cancer screening with prostate specific antigen. Medicina Clínica (English Edition). 2016 Oct 21;147(8):361-5.

[4] Salinas M, López-Garrigós M, Miralles F, Chinchilla V, Ortuño M, Aguado C, Marcaida G, Guaita M, Carratala A, Díaz J, Yago M. Evaluation of PSA testing by general practitioners: regional study in the autonomic Community of Valencia. Archivos Espanoles de Urologia. 2011 Jun 1;64(5):435-40.

PRAISE-U Achievements within the 1st year

Published Manuscripts:

- Májek, O.; Babjuk, M.; Roobol, M.J.; Bratt, O.; Van Poppel, H.; Zachoval, R.; Ferda, J.; Koudelková, M.; Ngo, O.; Gregor, J.; et al. **How to follow the new EU Council recommendation and improve prostate cancer early detection: The Prostaforum 2022 declaration**. Eur. Urol. Open Sci. 2023, 53, 106–108
- Van Poppel, H., Roobol, M. J., & Chandran, A. (2023). **Early Detection of Prostate Cancer in the European Union: Combining Forces with PRAISE-U**. *European urology*, *84*(6), 519–522. https://doi.org/10.1016/j.eururo.2023.08.002
- Gómez Rivas, J., Leenen, R. C. A., Venderbos, L. D. F., Helleman, J., de la Parra, I., Vasilyeva, V., Moreno-Sierra, J., Basu, P., Chandran, A., van den Bergh, R. C. N., Collen, S., Van Poppel, H., Roobol, M. J., Beyer, K., & On Behalf Of The Praise-U Consortium (2023). **Navigating through the Controversies and Emerging Paradigms in Early Detection of Prostate Cancer: Bridging the Gap from Classic RCTs to Modern Population-Based Pilot Programs**. *Journal of personalized medicine*, *13*(12), 1677. https://doi.org/10.3390/jpm13121677
- Beyer, K.; Leenen, R.; Ven-derbos, L.D.F.; Helleman, J.; Denijs, F.; Bramer, W.; Vasilyeva, V.; Briers, E.; Rivas, J.G.; Chloupkova, R.; et al. **Health Policy for Prostate Cancer Early Detection In the European Union and the Impact of Opportunistic Screening: PRAISE-U Consortium**. J. Pers. Med. 2024, 14, x. https://doi.org/10.3390/xxxxx

Accepted Abstracts:

- Beyer K., Leenen R., Venderbos L.D.F., Denijs F., Helleman J., Chloupkova R., Májek O., Briers E., Vasilyeva V., Gomez Rivas J., Annemans L., Vynckier P., Basu P., Chandran A., van den Bergh R.C.N., Collen S., Stenzl A., Van Poppel H., Roobol M.J.. **Why is there a need to re-think Prostate Cancer early detection?** EAU24 Paris.
- Beyer K., Leenen R., Venderbos L.D.F., Helleman J., Denijs F., Gomez Rivas J., Vasilyeva V., Briers E., Chloupkova R., Májek O., Frese T., Vilaseca J., Vinker S., Vynckier P., Annemans L., Basu P. , Chandran A., van den Bergh R.C.N., Collen S., Van Poppel H., Roobol M.J. **Understanding the barriers to Prostate Cancer population-based early detection programs: the PRAISE-U BEST survey.** EAU24 Paris.

…and many presentations (e.g. EAU national society meeting, Adriatic Forum 2023, Norwegian Prostate Cancer day (…))..

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EUCanScreen (April 2024 – 2028)

Joint Action on Cancer Screening: Implementation of cancer screening programs

- The Europe's Beating Cancer Plan has called for a new EU-Supported Cancer Screening Scheme to assure high performance of cancer
- screening programs across all the Member States (MS). The general objective of EUCanScreen is to assure sustainable implementation of **high-quality screening for breast, cervical and colorectal** cancer as well as implementation of the recently recommended screening programs – for lung, prostate and gastric cancers.
- EUCanScreen will facilitate the reduction of cancer burden and achieving equity across the EU.

- The consortium is **bringing together well-performing screening programs to those that require substantial improvements.**
- Altogether 29 partnering countries are represented in the consortium, including 25 EU MS, Ukraine, Moldova, Norway and Iceland.

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Work package 8 : Facilitation of the new screening approach implementation

Task 8.3: Support to methodology and harmonisation of datasets of prostate cancer screening
Lead by EMC , also as representative of PRAISE-U (EAU)

Participants in this WP are for now:

Italy (Lombardy Region, Turin, Reggio Emilia, ISPRO)
Estonia
Lithuania
Slovakia
Czech republic (UZiS)
Slovenia
Spain (Basque region)
Germany (DKFZ,BIPS, Peter Albers),

and many others who will learn or share knowledge

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Conclusions

- We are in the next phase of population-based PCa screening
- The EU recommendation has opened the way to start to look at opportunities for nationally tailored programs
- Long-term follow-up of ongoing trials will be closely followed
- **PRAISE-U** will be the hub in combining science with implementation
- **EUCanScreen** will enhance our knowledge on population-based prostate cancer screening

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Thank you for listening

Praise u

SMART EARLY DETECTION OF PROSTATE CANCER

m.roobol@erasmusmc.nl

www.praise-u.eu

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