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REVIEW ARTICLE

# Swedish regional population-based organised prostate cancer testing: why, what and how?

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**ABSTRACT**

**Objective:** This study aimed to describe the regional, population-based, organised prostate cancer testing (OPT) programmes that are being introduced throughout Sweden: motives, structure, target population, diagnostic algorithm, quality control, outcomes, research, and future perspectives.

**Results:** In 2018, the Swedish National Board of Health and Welfare renewed their recommendation against screening for prostate cancer. Despite this, regional OPT was considered motivated to (1) improve cost-effectiveness compared with unorganised testing, (2) improve equity by giving every man in the target population a chance to make an informed choice, and (3) gain diagnostic and organisational knowledge. The OPT programmes are provided as a regional public healthcare service. They are coordinated by a national working group. The final target population is all men aged 50–74 years. Regional OPT offices use a national administrative system to organise all steps from sending invitation letters to prostate biopsy according to a strict diagnostic algorithm. General practice is involved for blood draw only or not at all. Data are registered in a national register (SweOPT); an annual report is published with the regions' performance on key indicators. At the end of 2024, 16 of the 21 Swedish regions had started OPT and invited 256,000 men with an average cumulative participation rate of 43%. A consortium co-ordinates OPT-related research. A general experience is that communication and organisational matters have been more challenging than medical decisions.

**Conclusions:** The Swedish population-based OPT programmes provide organisational experiences, diagnostic outcomes, and research results of value for future national prostate cancer screening programmes.

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## Introduction

Prostate cancer is the most common cancer in men in many parts of the world [1]. In Sweden, it is also the cancer that causes the most deaths among men. Prostate cancer has a protracted, symptom-free, localised phase when it can usually be cured, while it is usually incurable when symptoms develop. These circumstances make screening an attractive way to reduce morbidity and mortality. A large European randomised trial shows that regular screening of men aged 55–70 years with serum prostate-specific antigen (PSA) can reduce prostate cancer mortality by about as much as screening with mammography reduces breast cancer mortality [2–4]. The use of systematic prostate biopsies in these trials did, however, also cause substantial harm in the form of overdiagnosis and overtreatment. National health authorities around the world therefore recommend against population-based screening for prostate cancer, with the sole exception of Lithuania where PSA-based screening in primary care has been recommended since 2006 [5].

Despite the absence of recommendations for screening, unorganised PSA testing has become widespread in many countries, not least in Sweden [6]. This unorganised PSA testing is costly, ineffective, and leads to a more unfavourable balance between benefits and harms than organised screening [7]. To overcome the problems with unorganised PSA testing, regional, population-based, organised prostate cancer testing (OPT) programmes have been introduced in Sweden since 2020 [8].

In recent years, research has shown that the use of magnetic resonance imaging (MRI) of the prostate to select men with a raised serum PSA value for biopsy, combined with lesion-targeted rather than systematic biopsies, more selectively detects potentially life-threatening cancer and thereby reduce overdiagnosis [9–11]. These diagnostic advances and the

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inefficient unorganised PSA testing led the European Union (EU) Council in 2022 to encourage the evaluation of the feasibility of organised prostate cancer screening programmes [12].

The aim of this article is to describe Swedish OPT: background, motives, structure, diagnostic algorithm, quality control, results, related research and future perspective.

## Swedish OPT: background and motives

Sweden has a tax-funded, public healthcare system, provided by 21 independent regions. The National Board of Health and Welfare issues recommendations, for example on screening. Sweden has three national cancer screening programmes: one for cervical cancer, one for breast cancer, and one for colorectal cancer. The former two are managed by separate screening units in each region, while the latter has a central unit managing all invitations and the analyses of the primary screening test. Invitations to these programmes are sent by letter from the screening units; primary care is not involved. On international comparison, the Swedish cancer screening participation rates are high [13].

In 2018, the Swedish National Board of Health and Welfare updated its recommendation on screening for prostate cancer with PSA tests and systematic biopsies. It maintained its previous advice against a national screening programme, as it was not assessed that the benefits clearly outweigh the harms on a population level. Instead, the Board has since 2007 recommended that men who want to be examined for prostate cancer be offered information about the potential advantages and disadvantages and then be offered testing if they so wish.

Following the Board's decision against a national screening programme for prostate cancer, concerns about the resource-consuming, but inefficient, unorganised PSA testing led the Swedish Ministry of Health and Social Affairs to commission the Confederation of Regional Cancer Centres to standardise PSA testing. This led to the concept of regional OPT programmes. The main motives for starting regional OPT are:

- to improve cost-effectiveness compared with the widespread unorganised PSA testing
- to improve equity by giving every man in the target population a chance to make an informed choice
- to gain knowledge (diagnostic and organisational)

The National Board has approved regional OPT, as these motives were deemed relevant even in the absence of a national screening programme.

## Structural and organisational aspects

### *Provision and funding*

OPT is provided and funded as part of the regional public healthcare services. In many regions, OPT started as a project, while in others there was an up-front decision to gradually launch a full-scale programme covering the entire target population.

### *Regional OPT offices*

The OPT programmes are operated by specific OPT offices, each managing OPT in one or a few regions. The OPT offices manage mail invitations, referrals to follow-up investigations, and notifications of test results. They also record outcome data for quality control. Most provide individual telephone advice about OPT and cooperate with a professional communicator for public information. The offices are staffed with administrative professionals, specialist nurses, urologists and radiologists. A national cooperation group for OPT offices was created in 2023.

### *National coordination*

In 2019, the Confederation of Regional Cancer Centres founded a National OPT Working Group. The group has representatives from the six regional cancer centres, typically one urologist and one project leader from each centre, and co-opted experts on prostate cancer screening, prostate MRI, clinical chemistry, nursing, and medical ethics. They are supported by a team from Regional Cancer Centre West, including information technology experts, professional communicators and statisticians. The group has two physical and three online meetings per year. Its purposes include:

- being a forum for the exchange of experience from OPT
- annually updating recommendations for OPT (available at www.cancercentrum.se)
- annually compiling and analysing key performance indicators for the regional programmes
- coordinating OPT development projects, such as the evaluation of alternative diagnostic algorithms and communication methods.

### *Administrative system and regional registries*

An administrative system for automatically sending out letters for invitation and result notifications has been developed. It is located on a national online platform for cancer services. Specific templates for recording MRI findings, prostate biopsies and prostate biopsy results are available on the platform [14] (Figure 1). Data are automatically transferred to regional OPT registers and the national OPT register (SweOPT), located on the same platform.

### *Information material*

The invitation to OPT and notifications of any subsequent results from PSA tests and MRI scans are sent by mail (paper or digital). Although each region is responsible for its own information material, there is agreement that the invitation letter's description of the potential advantages and disadvantages of prostate cancer testing should be the same throughout Sweden. A brief text was developed by the National OPT Working Group with assistance from professional healthcare communicators. A preliminary version was tested on a sample of men from the target

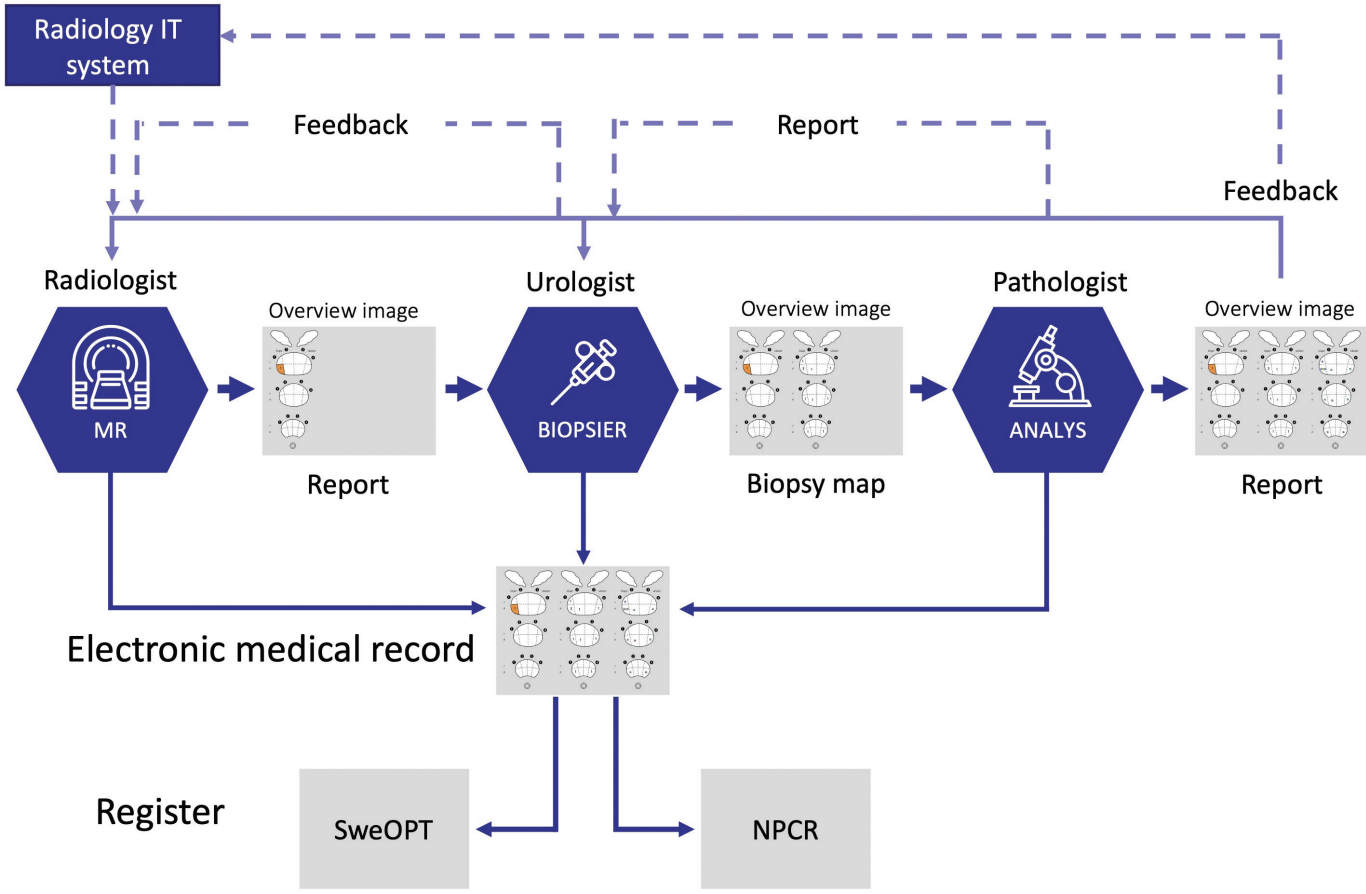


**Figure 1.** Integrated prostate MRI, biopsy, and pathology online reports, linked to the Swedish Register for Organised Prostate Cancer Testing (SweOPT) and the National Prostate Cancer Register (NPCR). Published with permission from the NPCR. MRI: magnetic resonance imaging.

population, which led to some adjustments before the final version was agreed upon.

The invitation letter mentions that more information is available at the public healthcare information site 1177.se, including a film. The film is translated into six languages; the Swedish version is also available with audio description.

Translations of the invitation letter from 2020 to 2023 were available online. Because of a small number of readers, the National OPT Working Group decided not to continue to translate information material about OPT. The decision is supported by a randomised study that showed that participation in breast cancer screening was not affected by whether the invitation was translated into various native languages [15]. The current text, used from January 2024, is written in so called 'Simple Swedish' to make it more easily understood by men not used to reading complex written information and by non-native Swedish speakers (Supplement).

### *Support for new OPT projects and simulation model*

Since 2022, a group at Regional Cancer Centre West has supported new OPT projects with practical matters before and during the implementation phase, for example IT support and handling of letters. Support is also provided for planning the expansion of OPT. A general experience is that communication and organisational matters have been more challenging than medical decisions.

Calculation of future resource needs is essential for a gradual implementation of population-based screening. A simulation model has been created that can be used by all regional OPT programmes. Some of the model's assumptions are well-founded based on results from OPT and screening studies, while others are uncertain. The assumptions are continuously reviewed in relation to OPT results and thereby gradually improved.

## Target population

A fully developed OPT programme includes all men aged 50–74 years. Most regions initially invited men in their fifties, as men who start screening before the age of 60 years reduce their risk of dying from prostate cancer more than those who start later [16].

One reason to continue OPT beyond the age of 70 years is that men live longer today than when the screening studies were conducted. Another reason is that lethal prostate cancer is more common in men aged 70–75 years than in younger men. With strict selection criteria for biopsy, high-risk cancers can be selectively diagnosed in this age group [17]. A third reason is that because the unorganised PSA testing in Sweden is most

common among men over 70 years of age, an upper limit of 70 years would likely lead to continued widespread unorganised testing among older men.

Just before sending a batch of invitation letters, the list of eligible men is crosschecked with the Cancer Register to exclude men already diagnosed with prostate cancer. The remaining men are, except in Region Värmland, invited without knowledge about any previous PSA tests or diagnostic procedures.

## Testing intervals and diagnostic algorithm

Swedish OPT is a long-term programme with active, repeated invitations and risk-stratified testing intervals. The testing intervals and the diagnostic evaluation of men with PSA ≥ 3 ng/mL are based on the Swedish national prostate cancer guidelines [18, 19]. Some minor adaptations to the specific OPT setting have been necessary, as described in the annually updated OPT recommendations [18, 20].

Men who choose not to be tested are re-invited after 2 years. Men with PSA < 1.0 ng/mL are re-invited after 6 years, while men with PSA 1.0 – 2.9 ng/mL and those with PSA ≥ 3 ng/mL and a negative diagnostic evaluation are re-invited after 2 years. A regional OPT office handles all steps from sending invitation letters to prostate biopsy according to a testing algorithm with dichotomous outcomes (Figure 2).

The standard OPT algorithm includes a prostate MRI scan for men with PSA ≥ 3 ng/mL. Men with a biopsy indication, defined by the MRI result and the PSA density (Figure 2), are referred to a urology service for a targeted and/or systematic prostate biopsy. A repeat PSA test is sampled before biopsy to confirm the biopsy indication. If no cancer is found on biopsy, the man is reinvited for a follow-up PSA test in OPT after 2 years (with some defined exceptions for men with a remaining high risk of cancer, who have a repeat biopsy).

In contrast to the Swedish national guidelines and the PROBASE screening trial protocol [21], the standard diagnostic algorithm for OPT does not include a confirmatory PSA test before MRI. Although MRI scanning would be avoided in men with a confirmatory PSA < 3 ng/mL, the National OPT Working Group does not consider this gain to outweigh the disadvantages: a confirmatory PSA sample would considerably increase the workload for the OPT offices, and it would be difficult to explain the cause and interpretation of differing PSA results in a letter, which might make some men obtain further PSA testing outside OPT.

The OPT philosophy of minimising individual management and follow-up of men with PSA ≥ 3 ng/mL in urology services works well for the first and second testing rounds, although OPT office staff sometimes have to intervene to make individual urologists comply with the diagnostic algorithm. With an increasing number of rounds, individualisation of repeat biopsy indications is unavoidable, as it is impossible to account for all potential changes in PSA density and MRI results (increased/decreased lesion size, etc.). If the urologist considers the man not well managed by the OPT algorithm (for example, because of recurrent urinary tract infections causing PSA peaks), the man is excluded from OPT and clinically followed up in urology.

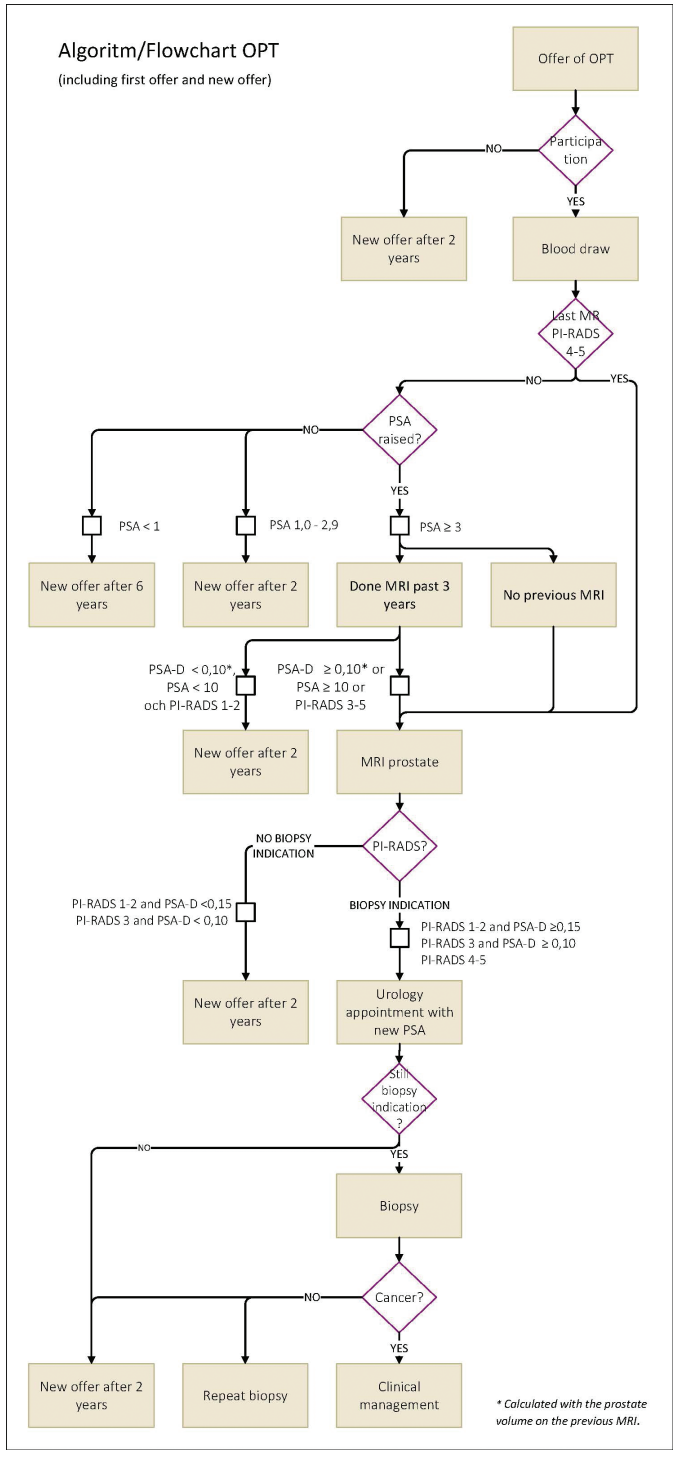


**Figure 2.** Standard diagnostic algorithm for Swedish organised prostate cancer testing (OPT). PSA-D: prostate-specific antigen density; MRI: magnetic resonance imaging; PI-RADS: Prostate Imaging–Reporting and Data System.

### *Ancillary tests to reduce the demand of MRI*

Five regional OPT programmes use alternative diagnostic algorithms. Four of them select men with PSA ≥ 3 ng/mL for MRI scanning at a urology appointment, where they have a confirmatory PSA, a digital rectal examination and a transrectal ultrasound for measurement of the prostate volume for calculation of the PSA density. Men with a clinically benign prostate and a

PSA density < 0.1 ng/mL/cm$^3$ are re-invited for a follow-up PSA test in OPT after 2 years, while the others are referred for MRI. One region uses the Stockholm-3 test (cut-off 15%) to select men with PSA ≥ 3 ng/mL for MRI [22, 23].

## Outcomes

OPT was first started in two regions in 2020 [8, 24]. The Covid-19 pandemic delayed further initiation of OPT, but from 2022 the number of regions with OPT has steadily increased. At the end of 2024, 16 of the 21 regions had started OPT and nearly 256,000 men had been invited. One region (Värmland) has already reached the entire target population of men aged 50–74 years. In 2025, three more OPT programmes will be started.

The results presented do not include the 44,000 invited men in Region Värmland, as this region does not report to SweOPT. The proportion of men choosing to participate, defined as having an OPT labelled PSA test any time following a first invitation to OPT, varied from 37% to 56% across regions, with an average of 43%. Over 3,500 MRI results have been registered, of which 70% were unsuspicious. Two thirds (68%) of the men who had a prostate biopsy in OPT were diagnosed with cancer; of these, 74% hade a Grade Group ≥2 cancer. Participation rates, MRI results, and biopsy results are displayed in Table 1.

## Data registration and quality control

A national online register platform was created in 2020. All regional OPT programmes except one enter all test results to the register, most often by automatic transfer from the administrative system. The integrated prostate MRI, biopsy, and pathology reports, used by many OPT programmes, allow for biopsy result feedback to the radiologist who scored the MRI scan [14] (Figure 1). In 2023, a national quality register for OPT was founded: SweOPT. Some SweOPT data are publicly available online at https://statistik.incanet.se/opt/.

**Table 1.** MRI and biopsy results at the end of 2024 in the 15 regional OPT programmes that had then reported to the national register SweOPT.

| Category | Number (percentage) of men |
|---|---|
| Invited | 212,530 (100%) |
| Participating (PSA tested in OPT) | 90,374 (43%) |
| MRI scanning results registered | 3,562 (100%) |
| - PI-RADS 1–2 | 2,504 (70%) |
| - PI-RADS 3 | 586 (16%) |
| - PI-RADS 4–5 | 472 (13%) |
| Prostate biopsy results registered | 1,244 (100%) |
| - Benign biopsy | 393 (32%) |
| - Grade Group 1 cancer | 222 (18%) |
| - Grade Group 2–3 cancer | 567 (46%) |
| - Grade Group 4–5 cancer | 62 (5.0%) |

As men with a PSA ≥ 3 ng/mL recorded late in 2024 may have their subsequent diagnostic evaluation reported in 2025, the final numbers of MRI and biopsy results will be somewhat higher. MRI: magnetic resonance imaging; PI-RADS: Prostate Imaging–Reporting and Data System; PSA: prostate-specific antigen; OPT: Organised Prostate Cancer Testing.

**Table 2.** Key performance indicators for Swedish organised prostate cancer testing (OPT).

| No. | Name |
|---|---|
| **1** | Testing algorithm |
| **2** | Age groups that are offered OPT |
| **3** | Proportion of men that are offered OPT |
| **4** | Proportion of men who have participated in OPT after invitation |
| **5** | Proportion of participants in OPT who have also provided PSA tests outside OPT |
| **6** | Proportion participating in further investigation |
| **7** | Assessment of MRI |
| **8** | Lead times |
| **9** | Prostate cancer diagnostics outside OPT among OPT participants |
| **10** | Proportion of participants with indication for prostate biopsy according to MRI who have undergone biopsy within OPT |
| **11** | Biopsy results |
| **12** | Proportion of participants diagnosed with prostate cancer |
| **13** | Proportion of participants receiving curative treatment for prostate cancer |
| **14** | Sensitivity of the test algorithm to detect serious prostate cancer |
| **15** | Total incidence of advanced prostate cancer in the region |
| **16** | Proportion of participants hospitalised for infection after prostate biopsy |
| **17** | Socioeconomic equality |

MRI: magnetic resonance imaging; PSA: prostate-specific antigen; OPT: Organised Prostate Cancer Testing.

The National OPT Working Group has defined 16 key performance indicators (KPIs, Table 2). The SweOPT steering committee summarises the regions' performances on the KPIs in an annual report. Some KPIs still have too scarce data for reporting, for example, the regions' total incidence of advanced prostate cancer. The KPI for socioeconomic equality requires coding of neighbourhood level characteristics for income, education and country of birth. This coding is ongoing, and we expect to annually report socioeconomic equality in each regional OPT programme from 2026.

## Research based on OPT

The Swedish Consortium for Research on Organised Prostate Cancer Testing (SweCROPT) was formed in 2022 to coordinate OPT related research. SweCROPTs aims are to:

- create a forum to exchange scientific ideas and experiences related to OPT research
- facilitate cooperative research
- prevent parallel studies of similar research questions.

SweCROPT has six working groups:

*Working group 1: Register-based research on socioeconomic equity and diagnostic outcomes.* As the Swedish OPT programmes are the first of its kind, simple descriptive reports of participation rates and diagnostic outcomes are highly valuable [25]. The outcomes of the first invitation to 68,000 50-year-old men have been published [26]. More detailed reports on MRI results and PSA density versus biopsy results, and on the outcomes of

subsequent testing rounds are underway. SweOPT can be linked with any of the many nationwide, highly accurate Swedish registers. One study using individual-level socioeconomic data and another using neighbourhood-level data showed that education, income, marital status, and country of birth were associated with the participation rate [27, 28]. The magnitude of these associations were similar to what has been reported from established cancer screening programmes [29].

*Working group 2: Improving diagnostic imaging.* Artificial intelligence (AI) may reduce the radiologists' workload for reading prostate MRI, but none of the commercially available prostate MRI AI programs have been trained on a screening population. A pilot study in an OPT population showed low agreement between expert radiologists' MRI scoring and a commercial AI program; the authors concluded that 'Training and validation of deep learning algorithms in specific screening cohorts are essential before introduction in organized testing' [30]. An evaluation on local versus central MRI reading has been submitted. A report on incidental MRI findings is being prepared.

*Working group 3: Biobanking.* Better biomarkers are needed to discriminate potentially lethal prostate cancer. A nationwide initiative to create an infrastructure for biobanking blood and tissue samples from men with suspected or confirmed prostate cancer, including those in OPT, has received considerable funding and will be launched in 2025: Swedish PRostate cancer Initiative for Novel Treatment Regimens (SPRINTR).

*Working group 4: Informatics and psychosocial aspects.* Questionnaire and interview studies show that almost all men appreciate being invited to OPT, that the information about the potential disadvantages may be hard to understand, and that men are typically affected more by practical issues and personal views than by hard facts and statistics when they make their decision [31–33]. Repeated such studies are planned to evaluate the revised information text that was put into use in January 2025 (Supplemental material).

*Working group 5: Health economy.* Resource issues, cost-effectiveness, and other economic aspects are essential when healthcare authorities consider recommending population-based, organised screening [34]. Participation rates and diagnostic outcomes of OPT, with and without ancillary tests to select men for MRI, will be used for various health economy studies.

*Working group 6: European collaborations.* The OPT programmes in the regions Västra Götaland, Skåne and Stockholm are associated with the European, EU4Health funded, PRAISE-U consortium [35].

## Discussion and future perspective

The Swedish, population-based, regional OPT programmes are the first of its kind in the world. The OPT invitations are sent to all men in selected birth cohorts, letters (paper or digital) for invitation and notification of PSA and MRI results are automatically generated, and all data are entered to a national register for quality control and research. The infrastructure that has been built and the practical experiences from OPT may pave the way for a future national screening programme. The Swedish National Board of Health and Welfare is expected to re-evaluate its recommendation about prostate cancer screening within a few years.

Experiences from OPT that we believe apply in all countries that develop a new organised testing/screening programme include the following:

- the necessary shift to a population perspective often is difficult for healthcare professionals who are used to individualising the care of each patient
- the communication and organisational matters tend to be more challenging than medical decisions
- the value of detailed, prospective data registration for quality control.

As pointed out before [18, 19, 36–38], with valid collection, purposeful analysis, and user-friendly presentation of feedback, register data can provide pivotal information for improving healthcare by monitoring the implementation of new healthcare measures and guideline recommendations.

A feature of OPT that applies to only some other countries is that invitations to OPT and referrals for diagnostic investigations is, like the Swedish national cancer screening programmes, administered by specific OPT offices rather than by general practitioners. Another is that the Swedish personal identification numbers, in combination with the detailed and highly accurate national registers, facilitate communication with the target population and follow-up of results.

The average participation rate of 43% may seem low. One likely cause is the absence of a national recommendation for prostate cancer screening; a recommendation for screening from the Swedish National Board of Health and Welfare would likely greatly increase participation. That mainly men in their fifties have been invited also contributes to low participation: older men are more likely to obtain PSA tests [6]. The 10-year prevalence of PSA testing among men aged 60–69 years was 74% in Region Stockholm in 2016. At least as high participation can be expected in a future national screening programme. Use of reminders to non-participants, yet sent in one region only, would probably also increase participation. The widespread unorganised PSA testing probably also reduces OPT participation as some men may recently have had a PSA test when invited to OPT.

Informing about potential advantages and disadvantages of screening for prostate cancer is a challenge. Although the benefit of a reduced risk of dying from the disease is easy for lay people to understand, the potential harms are difficult – particularly the concept of overdiagnosis [39]. A long, detailed information text may be enlightening for those who actually read it, but the longer the text the less likely it is that men read it through. There is an obvious need for research about how best

to inform men about prostate cancer screening. The optimal amount and form of information is likely different for men who themselves ask for testing versus for those who are invited by letter; it also differs across countries.

In most countries, MRI resources will be a bottleneck when population-based screening for prostate cancer is implemented. Ancillary tests to reduce the need for MRI are currently used in five of the Swedish OPT programmes. Evaluation of the cancer detection outcomes in these regions will help optimise their use. The utility of the Stockholm-3 test was prospectively evaluated in one regional OPT programme in 2024 (results are being analysed). The 4KScore test was retrospectively evaluated in the Göteborg-2 screening trial [40] and is being prospectively evaluated in the Finnish ProScreen trial [41].

To conclude, population-based OPT programmes are running in an increasing number of Swedish regions. Organisational experiences, detailed register data on diagnostic outcomes, and ongoing multifaceted research related to OPT will be valuable for future implementation of national prostate cancer screening programmes, not only in Sweden but also in other countries with a similar healthcare structure.

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