Organised Prostate Cancer Testing (OPT)

Description and Recommendations

Updated in 2026

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REGIONALA CANCERCENTRUM I SAMVERKAN

Version control

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7.1	2026-03-24	Typos corrected
7.2	2026-06-12	Key performance indicator list updated

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Responsible Regional Cancer Centre: Regional Cancer Centre West

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CHAPTER 1

Summary

1.1 Background to the recommendations

In 2018, the Swedish Ministry of Health and Social Affairs commissioned the Swedish Association of Local Authorities and County Councils (now the Swedish Association of Local Authorities and Regions, SKR) to standardise and streamline PSA testing and to identify gaps in knowledge about supplementary diagnostic tests for prostate cancer. In the same year, the Confederation of Regional Cancer Centres developed recommendations on organised prostate cancer testing (OPT). Since 2019, the Confederation of Regional Cancer Centres has a National OPT Working Group with representatives from the six RCCs and co-opted experts. The working group updates the recommendations every year.

In 2018, the Swedish National Board of Health and Welfare updated its recommendation on screening for prostate cancer. They still advise against a national screening programme, as it was not assessed that the benefits clearly outweigh the negative effects at the population level. However, the National Board of Health and Welfare points out that the healthcare system can contribute to increased knowledge by offering organised PSA testing within the framework of research and development. The National OPT Working Group (NAG OPT) was created in 2019. Since then, the group has issued annual updates of the background of OPT and recommendations on how OPT should be carried out. NAG OPT has also described OPT in an international scientific journal. [1]

1.2 Changes since the previous version (2025)

- The description of ongoing and planned OPT has been updated (Chapter 3).
- The standard algorithm has been supplemented with a specific algorithm for men who have undergone prostate biopsy (Section 6.8.2 and Appendix 5).
- The list of quality indicators has been revised and adapted to recently published European guidelines. SweOPT is now the first quality registry to register socio-economic variables at the area level (DeSO), enabling the annual reporting of indicators that quantify socio-economic inequality (Section 7.2 and Appendix 3).

CHAPTER 2

Background

2.1 Prostate cancer and prostate cancer diagnostics

Prostate cancer is the most common cancer in Sweden and the one that causes most deaths among Swedish men. Prostate cancer has a very long symptom-free, localised phase, where it can usually be cured, while it is almost always incurable when it causes symptoms. These circumstances make screening an appropriate method to reduce morbidity and mortality from prostate cancer. A large European randomised study has shown that regular screening of men aged between 55 and 70 years with the blood test for prostate-specific antigen (PSA) reduces prostate cancer mortality about as much as screening with mammography reduces breast cancer mortality [2, 3]. A Swedish randomised study has shown that PSA screening every two years, starting between the ages of 50 and 64 years, almost halves prostate cancer mortality after 14 years [4]. A recently published long-term follow-up of this study shows that men who start screening at age 50–55 years reduce their risk of dying from prostate cancer significantly more than those who start at age 60 years or later [5].

Many middle-aged and older men have a small prostate cancer that never progresses to life-threatening disease. Screening with PSA tests, followed by systematic tissue sampling, can therefore cause overdiagnosis and overtreatment [2, 4, 6, 7]. About half of the men diagnosed with prostate cancer after PSA screening and systematic tissue sampling would not have become prostate cancer patients if they had not been tested for PSA [2, 4, 6, 7]. Most men diagnosed with a small prostate cancer are treated with surgery or radiotherapy, which leads to side effects that can reduce their quality of life. One measure of the extent of overdiagnosis is the number of additional individuals diagnosed with cancer for each death prevented (*Numbers Needed to Diagnose*, NND). In the Swedish screening study, after 14 years of screening, 12 additional men had received a prostate cancer diagnosis for each prostate cancer death prevented, compared with men who had not been invited to screening and who had been PSA-tested to a small extent in routine healthcare (NND = 12) [3]. After 18 years of follow-up, the NND was 10 [8].

In recent years, research has shown that blood tests and MRI can supplement the PSA test to identify the men who need tissue sampling, which reduces overdiagnosis of non-life-threatening prostate cancer [9-13]. The diagnostic value of these supplementary tests is clear, but further research is needed to determine how best to use them and to what extent they can reduce overdiagnosis.

2.2 The screening recommendations of the National Board of Health and Welfare

The National Board of Health and Welfare advises against systematic screening for prostate cancer, as it was not assessed that the benefits clearly outweigh the negative effects at the population level (overdiagnosis and overtreatment) [14]. Instead, the National Board of Health and Welfare recommend that men who want to be examined in order to diagnose a possible prostate cancer early should be offered information about the possible benefits and harms and then be offered testing, if they so wish [14]. Almost all healthcare authorities in the world have similar recommendations. Screening is recommended only in Lithuania, Mexico and Czechia. In Lithuania, PSA testing has been performed in primary care since 2006 without a specific diagnostic pathway for men with elevated PSA levels. Mexico has a national recommendation for screening, but no organisation responsible for introducing a population-based programme. In Czechia, a national screening programme was launched as a pilot in January 2024. It will be evaluated after five years.

2.3 The assignment from the Ministry of Health and Social Affairs

In 2018, the Swedish Ministry of Health and Social Affairs commissioned the Swedish Association of Local Authorities and County Councils (now the Swedish Association of Local Authorities and Regions, SKR) to standardise and streamline PSA testing and to identify gaps in knowledge about supplementary diagnostic tests for prostate cancer. In the same year, the Confederation of Regional Cancer Centres developed recommendations on organised prostate cancer testing (OPT) and in 2019, they appointed a National OPT Working Group with representatives from the six Regional Cancer Centres (RCC) and co-opted experts.

2.4 The National Board of Health and Welfare's approach to OPT

OPT aligns well with the guidelines of the National Board of Health and Welfare. In 2018 [14], the National Board of Health and Welfare stated that "there is extensive, unorganised PSA testing of men in Sweden today. Testing often takes place without the men being adequately informed about the possible consequences of the testing. In addition, a large proportion of the men tested are over the age at which PSA screening has been shown to reduce prostate cancer mortality." and "Organised PSA testing means that men are given clear information about the

benefits and harms of the PSA test and subsequently make individual decisions about whether or not to get tested. Organised PSA testing should therefore not be confused with a national screening programme where testing is recommended by sending a direct invitation to be tested to men. The implementation of organised PSA testing in the context of research and development is fully in line with the recommendations from the National Board of Health and Welfare in the national guidelines for prostate cancer. The assignment of the RCC will not only increase knowledge about PSA testing, but also lay the foundation for an improved organisation of prostate cancer testing. An organisation that can be linked to a possible screening programme in the future. The National Board of Health and Welfare warmly welcomes these initiatives, which may lead to increased knowledge and more equal and effective diagnosis of prostate cancer."

The health-economic analysis of the National Board of Health and Welfare suggests that PSA screening would increase the number of quality-adjusted life years in the population and, in the long run, be cost-saving for society, compared to the current widespread, unorganised PSA testing [14].

2.5 The European Union's position on screening for prostate cancer

In December 2022, the EU Council of Ministers decided to extend their recommendations on screening for cancer to also include prostate cancer, lung cancer and (in parts of the Union) stomach cancer [15]. For prostate cancer screening, they recommend evaluation and gradual implementation in order to fill knowledge gaps and create an infrastructure for quality-assured testing, which is very similar our Swedish OPT initiatives: "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 programmes 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." Experiences and results from Swedish OPT are very valuable for the pilot programmes that are now beginning in the member states of the EU within the EU-funded project PRAISE-U [16].

2.6 Possible benefits and harms of OPT

There is consensus that the current widespread unorganised PSA testing is unequal, inefficient and very resource-intensive. In the absence of a national screening programme, other measures are needed to counteract the negative consequences of unorganised PSA testing. One such measure is to organise prostate cancer testing for men in appropriate age groups who, after being informed of the possible benefits and harms, wish to be tested. In this case, for reasons of

equality, all men in the relevant age groups should be informed about the possibility of being tested for prostate cancer.

In 2018, an expert group created by the Confederation of Regional Cancer Centres identified the following benefits and harms of replacing the unorganised PSA testing with organised, informed prostate cancer testing.

2.6.1 Possible benefits

- *Reduced morbidity and mortality*. Unorganised PSA testing does not reduce prostate cancer mortality as much as organised screening [6], in part because many men with elevated PSA levels are not investigated further and because the wrong age groups are tested [17]. Organising the prostate cancer testing is therefore likely to lead to reduced morbidity and mortality of prostate cancer.

- *Reduced resource consumption and reduced costs for treatment of advanced prostate cancer:* Over time, organised testing is likely to reduce the incidence of locally advanced and metastasised prostate cancer, which means that the resource requirements and costs of advanced prostate cancer will also be reduced.

- *More efficient use of resources*. In unorganised testing, each individual PSA test is assessed by a doctor who communicates the test result to the man either when meeting face-to-face, by phone or by letter. In OPT, administrative staff use computerised algorithms to manage information, appointments and test results. Unorganised PSA testing more often leads to overdiagnosis of non-life-threatening cancer, making the harm-benefit ratio less favourable than for organised testing [6]. Finally, today's routine healthcare spends considerable resources on close follow-up and repeated examinations of men with elevated PSA levels, who were not found to have cancer after tissue sampling. An analysis of the Gothenburg screening study shows that it is sufficient to follow up these men with a new examination appointment after two years [18].

- *Reduced resource consumption in primary care*. Most PSA tests in men without prostate cancer are performed in primary care, where each test result is assessed and responded to individually by a doctor. Thus OPT reduces the workload in primary care. With a fully developed OPT, PSA testing in primary care should only be prescribed in cases of clinical suspicion of prostate cancer and as a follow-up for men with elevated PSA levels outside the age group covered by OPT. Symptom-free men between the ages of 50 and 74 years who want to be tested for prostate cancer should be referred for OPT.

- *Increased equality*. Prostate cancer mortality is higher among men with a short education [8]. Results from the Gothenburg screening study indicate that systematic screening evens out this difference [8]. A Swedish study has shown that PSA testing is more common among well-educated men and that men with a short education are more frequently not investigated for elevated PSA levels [17]. Another study has shown that men with a short education are significantly less aware of the negative consequences of PSA testing than college graduates [19]. Only organising the testing is not sufficient to even out these

inequalities [20], but OPT provides the conditions for targeted measures and systematic evaluation.

- *Increased knowledge of new diagnostic methods*. The Ministry of Health and Social Affairs gave an assignment to identify gaps in knowledge about supplementary diagnostic tests. Results from OPT contribute to filling these knowledge gaps.

- *Increased knowledge of organisational aspects*. The investigation by the National Board of Health and Welfare revealed gaps in knowledge about organisational aspects of prostate cancer screening [14]. OPT provides valuable organisational experience for a possible future national screening programme, such as increased knowledge about practices for offering testing, information to men, practices for men with elevated PSA levels, how to reduce PSA testing in age groups outside the programme, and how to evaluate the programmes.

2.6.2 Possible harms

- *Men who are invited to participate may perceive the invitation as a recommendation*; they may therefore not read the information material on the benefits and harms of testing.

- *Increased resources for prostate cancer diagnostics*: Systematic information and invitations to prostate cancer testing for men between the ages of 50 and 74 years will initially increase the need for resources for diagnosis and treatment. The size of the increase will depend both on how widespread PSA testing is in the region prior to the introduction, and on the extent of PSA testing outside the programme.

- *Increased resources for treatment of localised prostate cancer*: OPT will, at least initially, lead to increased resource requirements for active monitoring, surgery and radiotherapy.

2.7 Ethical considerations

The investigation on prostate cancer screening by the National Board of Health and Welfare includes ethical considerations [14], which also largely apply to OPT. The National Board of Health and Welfare highlights the importance of ethical considerations regarding overdiagnosis, information prior to an invitation to participate, tests involving genetic markers and crowding-out effects. An ethical analysis has also been carried out as part of the preparations in Region Skåne. The same considerations emerged, but also that organised testing can compensate for inequalities between men with different levels of education.

Information issues are highlighted in section 3.4 National information material. The risk of overdiagnosis must be made clear in the information provided to men. A survey of men who had been invited to OPT in the Västra Götaland Region and in Region Skåne showed that 97 per cent of the men were very positive (84 %) or positive (13 %) about receiving a letter home with information about PSA testing and an invitation to get tested [21].

Healthcare assumes a special responsibility when healthy people are actively invited to testing to detect potential diseases. Before initiating and expanding organised prostate cancer testing, available and necessary resources must be investigated and assessed, including for diagnosis, active monitoring, treatment and rehabilitation. Men who are notified of test results above the threshold should be investigated and treated with the same objectives as for the standardised healthcare pathway. Crowding-out effects must be taken into account.

CHAPTER 3

Ongoing and planned OPT

Regional OPT was initiated in the autumn of 2020 in Region Skåne and in the Västra Götaland Region. These two regions cooperated during the preparation and implementation phases, including in the development of an IT system and regional registries on the INCA platform [22]. The COVID-19 pandemic caused many regions to downgrade the preparations for OPT until spring 2022. Thereafter, the activity increased significantly. The six RCCs have a coordinating function for their respective healthcare regions. Below, the situation in the six healthcare regions is described in brief.

3.1 South Healthcare Region

In the autumn of 2020, Region Skåne conducted a pilot project with 1,000 men [23]. Since 2021, OPT is offered to all men at age 50. The number of age groups invited for the first time has gradually increased. Since 2024, all men aged 50, 56 or 62 are included; in 2025, those aged 60 were also included. Re-invitations are issued in accordance with the standard algorithm.

In October 2025, OPT was introduced in Region Kronoberg for men aged 50 and 56 years. Region Blekinge plans to start in 2027. Region Halland awaits recommendations from the Swedish National Board of Health and Welfare.

3.2 Västra Götaland Region

Since 2022, OPT is offered in the Västra Götaland Region (VGR) to all men turning 50 during the calendar year. Subsequently, the regional management has extended the project with one year at a time. In 2025, OPT therefore included all men born between 1970 and 1975. From 2026, the expansion of OPT will accelerate, and men born in 1969 and 1976 will also be invited. Re-invitations are issued in accordance with the standard algorithm.

3.3 South-East Healthcare Region

Region Jönköping County was the first region to develop a digital process for OPT. In 2023 and 2024, all 50-year-old men were invited to participate in OPT. Since 2025, men aged 56 and 62 years are also re-invited. Re-invitations are issued in accordance with the standard algorithm. The South-East Healthcare Region has a common office in Region Jönköping County, which with the

developed digital process also administers OPT in Region Kalmar County and Region Östergötland. Region Kalmar County introduced OPT in October 2024 and Region Östergötland in Match 2025 by offering OPT to men born in 1975.

3.4 Stockholm-Gotland Healthcare Region

Since 2022, Region Stockholm and Region Gotland offers OPT through a common office to all 50-year-old men, with re-invitations in accordance with the standard algorithm. A one-year evaluation of the Stockholm3 test was conducted in 2024.

3.5 Healthcare Region Mid Sweden

In 2015, Region Värmland started to provide active information about the possibility of prostate cancer testing to men aged between 50 and 75 years. In the autumn of 2022, these activities became OPT, with a testing algorithm and organisation that differ from those in other regions. The Stockholm3 test is used to reduce the need for MRI. Since 2023, pilot projects are being conducted in the regions of Sörmland, Gävleborg, Västmanland, Örebro County, Dalarna and Uppsala, administered by a regional office in Uppsala.

3.6 North Healthcare Region

From 2022 to 2024, the regions of Västerbotten, Norrbotten, Västernorrland and Jämtland-Härjedalen introduced OPT. From the beginning, all these regions have offered OPT to men aged 50 and 56 years, with re-invitations in accordance with the standard algorithm; in Jämtland-Härjedalen also to 62-year-olds. In all the regions, political decisions have been made to extend OPT to the entire target group of men aged 50-74 years. The testing is coordinated by a common office at RCC North. An alternative testing algorithm is used: Men with PSA above the threshold are examined with palpation and ultrasound for calculation of the PSA density in order to select who need to proceed to prostate MRI.

CHAPTER 4

National coordination

4.1 National OPT Working Group (NAG OPT)

Since 2019, the Confederation of Regional Cancer Centres has a National OPT Working Group (NAG OPT) consisting of a chairperson and two representatives from each RCC. Experts on prostate cancer screening, prostate MRI, nursing and IT, as well as the two national cancer screening coordinators and a medical ethics officer are being co-opted to the group. RCC West supports NAG OPT with a coordinator, a registry product owner, communicators and statisticians. The current members of the working group are listed in Appendix 1.

The following reference groups receive copies of the minutes of the meetings: the Swedish Society of Radiology (SFMR), the Swedish Association of General Practice (SFAM), the Swedish Society for Clinical Chemistry (SFKK), the Swedish Urological Association (SUF), the National Society of Urology Nurses (RSU), the Swedish Society of Pathology (SvFP) and the Swedish Prostate Cancer Federation (PCF).

The Confederation of Regional Cancer Centres has commissioned the National OPT Working Group with:

- providing a forum for the exchange of experience for capitalising on lessons learned from regional OPT, conveyed by representatives of the respective RCCs;
- annually updating recommendations and information material related to OPT, in collaboration with the National Prostate Cancer Care Programme Group;
- being a specifier for the generic appointment and follow-up system on the INCA platform and the national quality registry for OPT;
- being a specifier for the national support office for initiating OPT;
- annually compiling and analysing the quality indicators for regional OPT;
- being a consultative body for regional OPT research and development projects, such as evaluation of supplementary diagnostic methods, variants of testing algorithms, organisation and implementation experiences.

4.2 Shared administrative system on the INCA platform

Before the start of OPT in Region Skåne and VGR, a common administrative system on the INCA platform for appointments and test results (OPT-IT) was developed, as well as regional healthcare registries for OPT (ROP). Since 2021, the assessment of MRI, the number and location of prostate biopsies and the histological assessment of the biopsies can be recorded on specific templates on the INCA platform that are linked to ROP (Appendix 2).

All regions should use OPT-IT, since a common IT system saves resources for development and operation, simplifies national reporting of results and facilitates the follow-up of men moving between different regions. OPT-IT is co-financed by the regions that use it.

4.3 National quality registry for OPT (SweOPT)

In the spring of 2023, a national quality registry for OPT was established at RCC West with VGR as the central data controller. The chairperson of NAG OPT is registry holder and the full members of NAG OPT are steering group. The registry is called SweOPT (Swedish Register for Organised Prostate Cancer Testing). The regional healthcare registries for OPT (ROP) are a part of SweOPT.

A large part of the information in SweOPT is freely available on the internet as an interactive report. It is possible to select the presentation based on several variables. Those who work with OPT in the regions can, after logging in, retrieve more detailed information about their respective results.

4.4 Communication, national information material

Since 2023, one or two communicators have been co-opted to NAG OPT. They are conveners of a group of regional communicators involved in OPT.

In 2019, NAG OPT produced a national generic text on the benefits and harms of prostate cancer screening. It has since then been revised several times. Since the translated versions at 1177 only had a small number of readers, NAG OPT decided in 2023 to no longer translate the generic text. The decision is supported by a randomised study showing that the proportion of participants in breast cancer screening was not affected by whether the invitation was translated into various native languages [24]. The current text (version 4.0), used since January 2025, is written in so called "Simple Swedish" to make it more easily understood even by the part of the target group who are non-native speakers of Swedish or who for some other reason may have difficulties reading complex written information.

From 2020 to 2024, the national text began with an explanation of why there is no national screening programme for prostate cancer. In the autumn of 2024, NAG OPT decided to remove this explanation, partly because it is difficult to write in "Simple Swedish" and partly because many men in the target group have pointed out that there is too much information in the letter, particularly when it is delivered in digital form.

The current text can be found in Appendix 4. More detailed information is available at 1177.se. An information film has been produced by RCC West in collaboration with several other regions. The film has been translated into six languages. The Swedish version is also available with audio description.

4.5 Regional information material

In addition to the nationally shared information, each region needs to develop its own regionally adapted information material, including information about where blood samples can be taken and what the regional testing algorithm looks like. In order to improve the effectiveness of the work and to develop the information and communication about OPT, NAG OPT has created a group of communicators which is open to representatives from all regions with OPT.

4.6 Implementation support for OPT

Since 2022, RCC West supports the regions' implementation of OPT, for example IT support and sending letters via Strålfors. A checklist has been produced. The group is led by the two national screening coordinators.

4.7 Collaboration with similar activities outside Sweden

The OPT activities in Skåne, VGR and Stockholm collaborate with an EU-funded project (PRAISE-U) for the implementation of screening for prostate cancer. PRAISE-U, which is led by the European Association of Urology, EAU, has received a grant of 10 million euros for 2023-2026 from the European Union's EU4Health programme [16]. As OPT in Sweden is much more advanced than the PRAISE-U pilots in other European countries, Sweden's role in the collaboration primarily involves the exchange of experience.

4.8 Research on and development of OPT

OPT provides excellent opportunities to evaluate and develop diagnostic methods and the organisation. Several regions are involved in innovative development projects, for example evaluation of variants of the testing algorithm, development of technology for and quality assurance of prostate MRI, development of digital communication with the target group and various alternative organisational solutions. These overarching development projects are discussed within NAG OPT before being initiated to ensure the best possible coordination.

Since 2023, research on OPT is being coordinated by a national consortium (SweCROPT). The consortium has six working groups: registry-based research on diagnostics and socio-economic aspects, diagnostic imaging, psychosocial aspects and informatics, biobanking, health economics and European cooperation. The consortium collaborates with NAG OPT on research based on comparisons between regional variants of the testing algorithm. The convener of the consortium is Ola Bratt at Gothenburg University (email: ola.bratt@gu.se).

CHAPTER 5

Organisational aspects

5.1 Basic principles

The update has not resulted in any changes to the basic principles:

1) Before starting OPT, the available and necessary resources must be investigated and assessed.
2) OPT should be planned, evaluated and reported so that the activities can contribute to filling important knowledge gaps on how to improve prostate cancer testing, through supplementary diagnostic tests and organisational measures.
3) Men who are invited to participate should receive balanced information about the potential benefits and harms of an early prostate cancer diagnosis.
4) OPT should cover all stages from information and testing to a potential prostate cancer diagnosis.
5) In order for OPT to both provide equal healthcare in accordance with guidelines of the National Board of Health and Welfare and help fill important knowledge gaps, the activities should be coordinated as described below.

5.2 Central office

For the day-to-day operation of OPT, a central office is required. Administrative staff at the central office can handle, among other things, mailings of information, appointments to follow-up prostate cancer tests, notification of test results, and recording of quality indicators. Nurses satisfying the need for personal information and care, as well as medical experts within urology and diagnostic imaging should be linked to the central office. The central offices should offer or refer to some form of telephone contact for men who have questions about the programme or who want to discuss their choice to participate or not. Since 2023, a cooperation group for the regional OPT offices has been in place, led by a member of NAG OPT.

5.3 Testing units

Blood sampling for PSA within the OPT framework should be provided near the residents. In most regions, testing in primary care is necessary to provide good accessibility outside the cities.

5.4 Diagnostic units

Investigation of men with test results above the threshold in OPT should take place in well-defined separate pathways at existing urology units or, when the volumes are sufficient, at

separate units. Experience shows that active action by the central office is required to prevent individualised management with follow-up by routine healthcare.

5.5 The role of primary care

Primary care is important for the blood sampling within OPT to be easily accessible outside major cities. In return, OPT saves resources in terms of doctors since PSA testing outside OPT is mainly done in connection with doctors' appointments in primary care. With a fully developed OPT, primary care should only prescribe PSA testing in in cases of clinical suspicion of prostate cancer and for follow-up of men with elevated PSA levels outside the age group covered by OPT.

5.6 Administrative system and regional registries

In order to provide a good basis for national evaluation of OPT, an administrative system for appointments and automatic letter replies has been developed on the INCA platform: OPT-IT. Information from OPT-IT is easily transferred to regional healthcare registries for OPT (ROP) and to the national quality registry for OPT (SweOPT), which are both available as a common function on INCA.

Special templates for prostate cancer diagnostics have been developed on INCA [25]. MRI findings, prostate biopsies and pathology results from prostate biopsies can be made directly on INCA, after which they are automatically transferred to SweOPT/ROP. All regional OPT activities should join OPT-IT, SweOPT/ROP and use the diagnostic templates on INCA in order to facilitate follow-up, quality control and research. There are specific programme councils for ROP and OPT-IT, where all regions with OPT can participate.

If a regional OPT activity chooses not to join the national systems on INCA and record relevant information there, the administrative system should be adapted so that the information can be easily transferred to the national quality registry SweOPT.

5.7 Simulation models for calculation of resource consumption

Since 2022, NAG OPT has a working group for simulating future resource consumption. Some of the assumptions upon which the models are based are well-founded on the basis of existing results from OPT and screening studies; others are more uncertain. The assumptions are reviewed continuously in relation to the results of OPT and other evidence.

5.8 Health-economic evaluation and planning

Health-economic analyses on the national level are being conducted on a research basis. If individual regions conduct health-economic analyses, they should be made available to the National OPT Working Group.

5.9 Measures to reduce unorganised PSA testing

Regionally adapted measures are required to avoid that symptom-free men are PSA-tested in parallel with OPT. In Sweden, PSA testing of older men is remarkably common (Figure 1). It is therefore an urgent matter to reduce PSA testing among men over 75 years of age without clinical suspicion of prostate cancer. However, the measures must not lead to men with symptomatic prostate cancer not being adequately investigated. In 2018, the general practitioners in the expert group appointed by the Confederation of Regional Cancer Centres estimated that symptom-free men over the age of 74 years can probably be advised against PSA testing, if there is an organised programme for men up to that age.

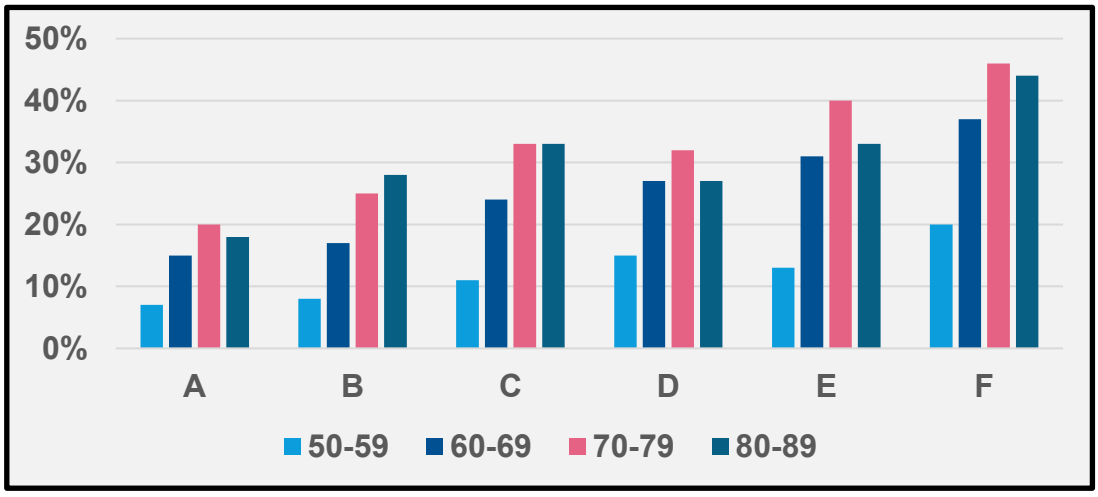

Figure 1. Proportion of men without known prostate cancer in six regions who had at least one PSA test in the calendar year 2015, by age group. Source: National Board of Health and Welfare.

CHAPTER 6

Recommendations for testing

6.1 Target group

A fully developed OPT programme should include all men aged 50 to 74 years. There is no direct evidence that screening over the age of 70 years is beneficial. One reason to continue, despite this, to follow men in OPT beyond the age of 70 years, is that men live longer today than when the screening studies were conducted. Men who are currently a few years older than 70 years of age are therefore as likely to benefit from an early diagnosis of prostate cancer as the men just under 70 years of age who participated in the screening studies. Another reason is that serious prostate cancer is more common in men aged 70 to 75 years than in younger men [26]. With strict selection criteria for tissue sampling, high-risk cancers can be selectively diagnosed in this age group [26]. A third reason is that PSA testing in Sweden is currently most common among men over 70 years of age. An upper limit of 70 years would therefore likely lead to continued widespread unorganised testing among older men.

When a participant in OPT moves to another region, he does not automatically receive a new invitation to PSA testing according to the schedule in the original region. For OPT participants with a medical need for follow-up, active transfer to the new region is required. From 2026, the product owner for OPT-IT will produce a list of all men in OPT with PSA ≥ 3 µg/L who have moved from one region to another during the previous six months, enabling the OPT office in the region of origin to send a letter with individual instructions for follow-up in the new region (within OPT, in primary care, or at a urology clinic). In the long term, it should be possible to manage transfers between regions digitally.

Some persons with a prostate have a female personal identity number. At present it is not possible for the regions to use a registry to identify these persons so that they can be invited to OPT, but most of them have, in connection with gender-affirming medical treatment, been informed that they themselves must take the initiative to undergo screening for conditions offered only to persons with the gender indicated by their previous personal identity number. Since the harm-benefit ratio of screening for prostate cancer is unknown for persons with a prostate who have undergone gender-affirming medical treatment, these persons are primarily recommended to discuss PSA testing with, for example, a urologist and, where appropriate, perform the testing outside OPT.

6.1.1 Blocking continued OPT invitations

Regions that offer OPT must be able to block individuals from receiving continued invitations. Since 2026, it is possible to register the reason in OPT-IT: the man's request, severe comorbidity or need for individual follow-up, for example owing to recurrent urinary tract infections, fluctuating elevated PSA levels or a suspected tumour that is difficult to diagnose or biopsy.

6.2 Implementation phase

A gradual implementation over several years is absolutely necessary. The pace must be adapted to the regional conditions. It is advisable to start by offering OPT to men aged between 50 and 56 years, since screening started in this age group reduces the risk of dying from prostate cancer considerably more than if screening starts at age 60 years or later [5].

One possibility is to begin by organising testing for men who are already being PSA-tested or are being followed up after previous tissue sampling where cancer was not detected. Then one can start to actively inform younger age groups and gradually include older men.

The period with parallel systems for OPT and unorganised testing should not be too long. Parallel systems may result in some men being tested both within OPT and in routine healthcare, which is an inefficient use of the limited resources for prostate cancer diagnostics. Moreover, organised testing for certain age groups may increase unorganised testing in other age groups.

6.3 Testing invitation and information

The nationally shared, generic text about the possible benefits and harms of prostate cancer testing should be sent out with the invitation to participate in OPT (Appendix 4). Since January 2024, the text is written in "Simple Swedish" to make it easier to understand for as many people as possible, including non-native speakers of Swedish and those not accustomed to reading complex written information. In a fully developed OPT, the information and invitation should be sent out every two years to men who are not already being followed within OPT; both to give men who have previously opted out another opportunity to participate, and because the evidence base – and therefore information about testing – may have changed since the previous invitation. In addition to the generic text, the invitation to OPT should be designed in accordance with the principles set out in Appendix 4.

The national information needs to be supplemented with regionally adapted information on practical issues, including where blood samples can be provided.

Digital communication within OPT has been developed and evaluated in Region Jönköping County. The evaluation shows that users are very satisfied. The proportion who underwent testing was somewhat higher than in other regions. More and more regions are using digital

information via the national digital information platform 1177, usually after an initial paper letter explaining that a digital invitation to OPT will arrive and that the man must registered with 1177 to receive further communication about OPT. Procedures for men who do not use computers or mobile phones are being developed. An evaluation of how digital communication affects testing in different socio-economic groups is being planned.

6.4 Patient charges

The charge, if any, for taking a PSA test and being investigated within the OPT framework is decided by the regions themselves. It is advisable to apply the same principles as for the ongoing national screening programmes.

6.5 Threshold for PSA testing

The threshold for further investigation should be 3 µg/L for all ages in the programme, unless the algorithm is a research project with supplementary testing. Men should be informed of their exact PSA level and what this level means for them.

The different methods of analysis for PSA that are being used in the regions produce somewhat different PSA levels, which causes considerable variation in the proportion of men who have a PSA level above the action threshold and thus are recommended further investigation [27]. NAG OPT has discussed this problem with representatives of clinical chemistry, who in their turn have raised the question with EQUALIS. NAG OPT subsequently discussed the possibility of allowing laboratories to adjust test results depending on the analytical method used, and of applying different thresholds for PSA or PSA density for further investigation. However, it concluded that the negative effects would be too great due to differences in PSA levels and assessments within and outside OPT. Since 2024, NAG OPT collects data on the methods of analysis used for OPT.

The National Healthcare Programme currently recommends a threshold of 5 µg/L for men between 70 and 80 years of age. However, in the case of OPT, it would be inappropriate to raise the threshold from 3 to 5 µg/L for an individual man between two samplings. Therefore, a threshold of 3 µg/L should be maintained until OPT is discontinued.

Ejaculation has been reported to slightly increase PSA levels in some men; however, the overall assessment is that men do not need to be advised against ejaculation prior to PSA testing in OPT.

For men treated with 5-alpha reductase inhibitors (finasteride/dutasteride), the healthcare programme indicates thresholds that are half of those above (limited evidence). Region Stockholm initially inquired about such medication in connection with blood sampling within OPT. The collected information about medication was often incorrect, which resulted in unmotivated continued investigation for some men. NAG OPT therefore advises against a

special testing algorithm for men with 5-alpha reductase inhibitors. Moreover, it would be difficult to adapt the testing algorithm to short-term or irregular medication.

6.6 Test intervals for men with PSA below the threshold

The test intervals should be the same throughout Sweden and as far as possible follow the recommendations of the National Healthcare Programme. Within OPT, the following intervals are recommended:

- PSA < 1 µg/L in men up to 68 years: new PSA test after 6 years
- PSA < 1 µg/L in men over 68 years: No further invitation
- PSA 1–2.9 µg/L: new PSA test after 2 years

6.7 Hereditary risk group

The National Healthcare Programme recommends earlier start of PSA testing (40 years), 2-year test intervals regardless of PSA level and lower action threshold for PSA for men in the hereditary risk group. NAG OPT has considered developing a specific algorithm in OPT for these men, so that they can be monitored within OPT until possible indication for biopsy, but decided against this approach since it is unclear how they should be identified in a safe way. Incorrect information about heredity may result in unnecessary testing. The regional OPT offices should establish procedures for the management of men who state significant heredity. Men who unambiguously meet the National Healthcare Programme's criteria for hereditary risk group should be offered a referral to a caregiver who can monitor them in accordance with the programme.

6.8 Management of men with PSA above the threshold

To be able to evaluate and develop the diagnostic algorithm, as many steps as possible should be governed by measurable variables with binary outcomes which minimises the room for individualisation of the investigation. This means that there are some differences compared to the National Healthcare Programme, which takes individual aspects into consideration. Appendix 5 describes the standard algorithm for OPT. Differences to the National Healthcare Programme 2024 are described and motivated in Appendix 6. Changes to the diagnostic recommendations in OPT are always made at the turn of the year.

As long as OPT generates only a small flow of patients to urology clinics, it may be difficult for urologists to adapt their clinical management to the OPT guidelines. The OPT offices should therefore monitor clinical management and, if necessary, contact the urology clinic to correct deviations.

6.8.1 Management of men with an initial PSA above the threshold

The following is recommended for OPT:

- Men with PSA ≥ 3 µg/L should undergo MRI of their prostate (see 6.8.3). The MRI findings should be graded according to PI-RADS.
- The PI-RADS assessment and PSA density govern the indication for biopsy.
- Before considering biopsy, the investigating urology unit should arrange for a new PSA test (recommendation since 2025). If the new PSA level is lower, this level should be the base for calculating the PSA density. If the indication for biopsy goes away, the new lower level should be registered in OPT-IT.
- PI-RADS 1–2 (no suspected tumour): Systematic biopsies for PSA density ≥ 0.15 µg/L/cm^3. Since 2023, the National Healthcare Programme recommends systematic biopsies for PSA density ≥ 0.2 µg/L/cm^3, but in that year, NAG OPT decided to maintain the threshold at 0.15 µg/L/cm^3 since 15 % of 50-year-old men in OPT with PI-RADS 1–2 and PSA-D 0.15–0.19 µg/L/cm^3 had cancer with a Gleason score of 7. However, Region Stockholm did raise the threshold to 0.2 µg/L/cm^3 from January 2024 to compensate for the fact that their method of analysis for PSA yields somewhat higher levels than the methods of the other regions.
- PI-RADS 3 (slight suspicion of tumour): Since 2024, targeted biopsies are recommended for PSA density 0.10–0.19 µg/L/cm^3 and targeted plus systematic biopsies for PSA density ≥ 0.20 µg/L/cm^3. From 2020 to 2023, the threshold was 0.15 µg/L/cm^3. The change is consistent with a change to the National Healthcare Programme.
- PI-RADS 4–5 (suspected tumour): Targeted biopsies, possibly supplemented with systematic or perilesional biopsies.

Management following an initial biopsy showing no evidence of cancer:

- PI-RADS 1-4 and PSA density < 0,3 µg/L/cm^3: repeat PSA testing within OPT after 2 years (unless the man belongs to the hereditary risk group, see section 6.7 above).
- PI-RADS 1-4 and PSA density ≥ 0,3 µg/L/cm^3: the MRI should be re-evaluated and PSA remeasured after 3 months; if PSA density remains ≥ 0.3 µg/L/cm^3, repeat biopsies should be performed within OPT.
- PI-RADS 5: the MRI should be re-evaluated; if still PI-RADS 5, repeat biopsies should be performed within OPT. If findings remain benign, the man should be withdrawn from OPT and followed up within the healthcare system.

Regions may choose to deviate from some parts of the standard algorithm. Such deviations should be discussed with the National OPT Working Group. The results from alternative algorithms should be compared with the standard algorithm, reported nationally and published in scientific journals.

In the four regions coordinated by RCC North, men with PSA ≥ 3 µg/L are examined with palpation and transrectal ultrasound for measuring the prostate volume and calculation of the PSA density. Men with benign palpation findings and a PSA density < 0.1 µg/L/cm^3 are considered to have a sufficiently low risk of prostate cancer requiring treatment to not have to undergo MRI.

Since 2023, the National Healthcare Programme recommends a new PSA test before considering MRI. The reason is that 15–20 % of these men have PSA < 3 µg/L in the follow-up blood test [28, 29]. Having men within OPT take an additional PSA test before MRI would decrease the resource requirements for MRI, but there are counterarguments that NAG OPT considers outweigh the benefits: a considerable increase in the workload for the central offices, uncertainty as to which PSA level should be used for calculation of the PSA density and difficulty in explaining the variation in the PSA levels in a letter. This could make the men choose to submit new PSA tests outside OPT. NAG OPT therefore do not recommend a new PSA test before MRI within OPT. In 2026, two regions will evaluate the effects of adding a PSA test before deciding whether to perform MRI. On the other hand, a new PSA test before considering biopsy is always motivated (see 5.8.1).

When follow-up within OPT ends at age 74 years, men with PSA above 10 µg/L should be referred to a urology clinic for individual assessment of the need for further follow-up. The assessment should be based on comorbidity and results from previous investigation.

6.8.2 Management of PSA above the threshold at follow-up test rounds

Since 2024, no new MRI is recommended for men with an MRI within the last 3 years with PI-RADS 1–2 and a current PSA < 10 µg/L with PSA density < 0.1 µg/L/cm^3 (previously, MRI was recommended for all men with PSA ≥ 3 µg/L). Since January 2025, all men with PI-RADS 4–5 at the previous MRI are referred for another MRI regardless of PSA level.

From 2026, men with PI-RADS 1–2 and previous benign biopsies will not undergo further investigation unless their PSA density has increased by ≥ 0.5 µg/L/cm^3 since the previous biopsy; instead, OPT-IT will initiate a letter informing them that they will be invited to repeat PSA testing within OPT after 2 years.

6.8.3 Guidelines for prostate MRI within OPT

Prostate MRI within OPT should be performed in accordance with the recommendations in the National Healthcare Programme for prostate cancer. Routine administration of contrast agents is not recommended. Within OPT, incidental findings have a different significance than in clinical diagnostics. Guidelines for the reporting of incidental findings within OPT are provided in Appendix 7.

6.8.4 Supplementary blood tests for PSA above the threshold

Supplementary blood tests can identify men with a moderately elevated PSA levels who have such a low risk of prostate cancer requiring treatment that they do not need to undergo MRI or prostate biopsy. The Stockholm3 test and 4Kscore have been evaluated in a screening-like setting

with MRI-based diagnostics and have been shown to reduce the need for MRI by 30–40 % without substantially affecting the detection of cancers with a Gleason score ≥ 7. [9, 13, 30].

There is still a lack of knowledge concerning to what extent these supplementary tests contribute to an algorithm that includes PSA density to select men for biopsy and concerning their value in case of repeated testing. NAG OPT and the National Healthcare Programme Group believe that regional OPT with registration of results in SweOPT/ROP is well suited for practical evaluation of these tests. In 2024, Region Stockholm conducted a research study within the OPT framework where 50-year-old men with PSA ≥ 2 µg/L were invited to a Stockholm3-test in order to select who need to proceed to prostate MRI. However, the National Board of Health and Welfare has made the assessment that the genetic part of the Stockholm3 test cannot be used in screening-like activities under the existing legislation. The decision was appealed but the highest reviewing authority upheld the assessment of the National Board of Health and Welfare.

CHAPTER 7

Follow-up and quality control

7.1 Regional registration of OPT data

The operation of OPT is entirely dependent on the central office having information about all individuals who will be invited to OPT and about all individuals who participate in the programme. Detailed information about invitation, participation, PSA levels and results of investigations for elevated PSA levels, including dates, must be recorded, preferably in the OPT-IT administrative system (5.7). Equally detailed information is required for evaluation, quality control and improvement of the activities. Since one rationale for implementing OPT is to fill gaps in knowledge, the demands on reporting the results are very high.

7.2 National reporting of quality indicators

National exchange of experience from regional OPT is crucial for the development of the algorithm and organisation of OPT. Since the beginning of 2023, there is a national quality registry for OPT (SweOPT) at RCC West. It is important that all regional activities record the variables required for the reporting of the OPT quality indicators. SweOPT openly publish reports of the extent and results of OPT in the regions at https://statistik.incanet.se/opt/.

NAG OPT has developed national indicators for OPT that are aligned with European recommendations [31] (Appendix 3). The indicators shall be used continuously for evaluation, quality control and improvement. All regions should record the necessary data for the indicators and annually report the outcome to the National OPT Working Group. The analysis by the National OPT Working Group should be used for evaluation, quality control and improvement of regional OPT. The indicators that are based on data that is available in SweOPT are published openly as interactive reports and in SweOPT's annual report.

CHAPTER 8

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APPENDIX 1

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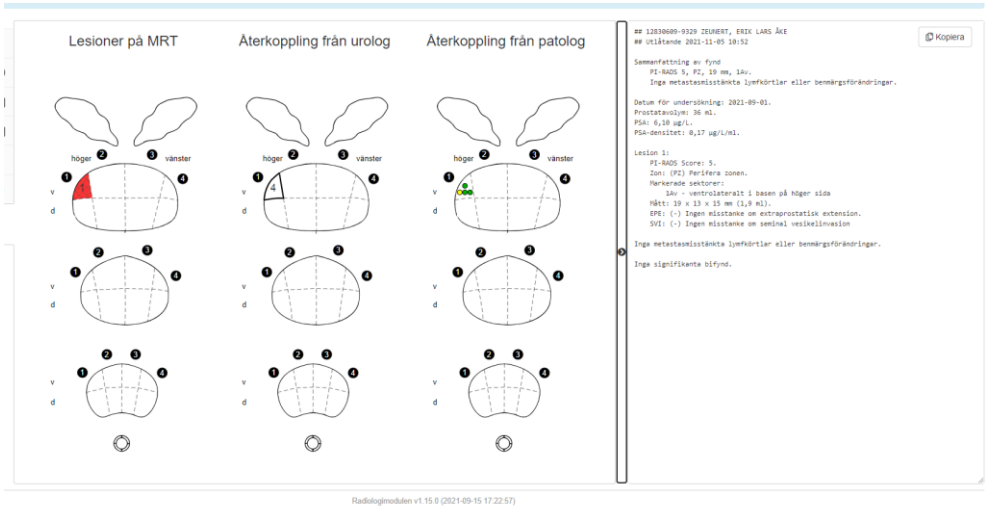
Declaration of conflicts of interest for the members of the working group

Prostate cancer diagnostics and treatment of early detected prostate cancer is a major part of the clinical and research activities of several members of the working group. Otherwise, no member of the group has declared any conflicts of interest relevant to the assignment.

APPENDIX 2

National template for registration of prostate cancer diagnostics



APPENDIX 3

Key Performance Indicators

No.	Name
1	**Algorithm**
2	**Coverage** 2a) Age groups invited to OPT 2b) Proportion of men invited to OPT
3	**Participation** 3a) Cumulative participation 3b) Participation within 6 months 3c) Participation following re-invitation of men with PSA ≥ 3 µg/l
4	**Test results:** Distribution of PSA < 1.0 / 1.0-2.9 / ≥ 3 µg/l
5	**Testing and diagnostics outside OPT** 5a) Testing both outside OPT among OPT participants 5b) Prostate cancer diagnosis outside OPT among OPT participants
6	**Adherence to diagnostic investigations** 6a) Adherence to the first diagnostic investigation 6b) Adherence to prostate biopsy
7	**Equity** 7a) Participation in testing in towns, villages and on the countryside 7b) Participation in diagnostic evaluation in towns, villages and on the countryside 7c) Participation in diagnostic evaluation depending on neighbourhood income 7d) Participation in diagnostic evaluation depending on country of birth
8	**Imaging** 8a) MRI assessment 8b) Incidental findings on MRI
9	**Time intervals** 9a: Time from PSA test to notification of MRI 9b: Time from MRI examination to notification of biopsy results 9c: Time from PSA test to notification of biopsy results
10	**Cancer detection** 10a) Outcomes of prostate biopsy within OPT 10b) Proportion of diagnostic investigations resulting in a cancer diagnosis within OPT 10c) Proportion of OPT participants diagnosed with prostate cancer within OPT
11	**Hospital care for infection following prostate biopsy**
12	**Advanced cancer** 12a) Advanced interval cancer 12b) Advanced cancer diagnosed in OPT 12c) Regional incidence of advanced prostate cancer
13	**Treatment** 14a) Curative treatment among OPT participants 14b) Curative treatment among participants with cancer 14c) Active surveillance for low-risk cancer

APPENDIX 4

Principles for OPT invitation

In February 2025, NAG OPT agreed on the following principles for the design of the OPT invitation:

1) The letter should begin with an explanation of why it is being sent, clearly stating that this is an invitation, not an appointment. What is offered should be described as "prostate cancer testing", "testing for prostate cancer", or "testing for the early detection of prostate cancer", rather than "PSA test" or similar.

The letter should include:

2) A brief description of benefits and harms. The wording should be identical across all regions (current version is provided on the next page):

- The most important benefit: regular testing increases the likelihood of detecting prostate cancer at a curable stage.
- The most important harm: overdiagnosis and overtreatment may lead to side effects and reduced quality of life.

3) A reference to where more detailed information can be found.

4) Contact details (digital/telephone) for those responsible for OPT in the region.

5) Information that the first step is a blood test.

6) A brief description of what happens after testing, depending on the PSA level.

7) Practical information on how the man should proceed to provide a PSA sample.

8) Information that data are stored in a quality registry, and that the man may opt out, including instructions on how to do so.

Men who are referred for MRI should be informed about potential incidental findings. The text should be the same in all regions: "Sometimes the examination shows something outside the prostate which may be of significance for your health. In this case we will contact you."

National text for OPT invitation

Version 4.0, used from January 2025

The following text should be used verbatim in invitations for testing in all regions. Of course, regions can choose to add additional information to their mailings. Since 2025, the text is included in 1177's information on PSA testing. The text is being revised; a new version will be used from January 2027.

Benefits and harms of getting tested

There are both benefits and harms of getting tested regularly for prostate cancer. Here you can read about some of the most important ones. You can read more about PSA testing and prostate cancer at www.1177.se.

Benefits

- Prostate cancer is easier to find early if you get tested regularly.
- If the doctor finds a dangerous prostate cancer, you will get treatment right away. In this case it is usually possible to cure the disease and you can get well again.

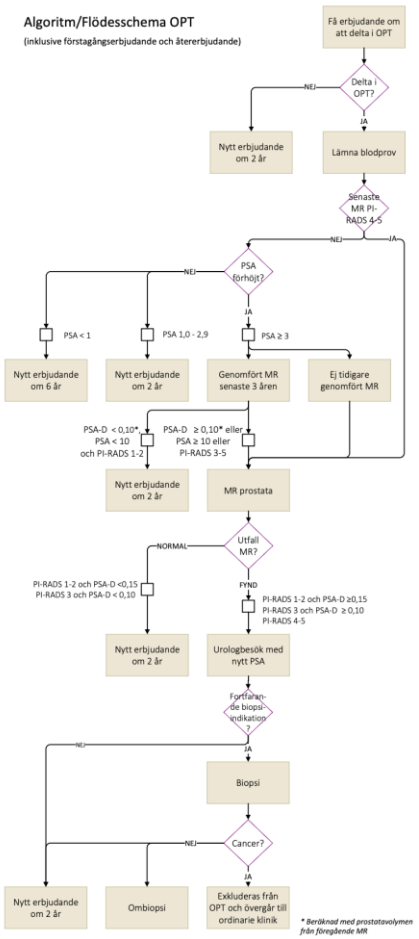
Harms

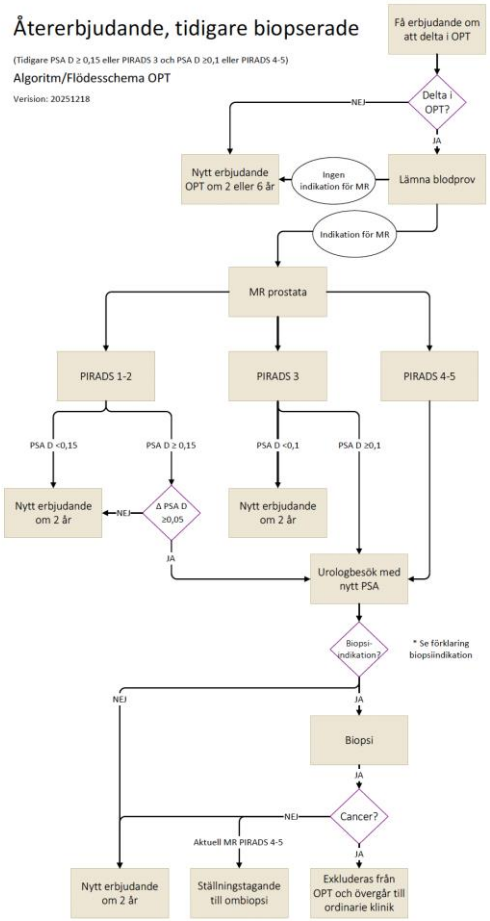
- Sometimes you do not need treatment for prostate cancer. For example if the cancer is growing slowly. In this case the cancer may be harmless. This is common. You may feel uncomfortable about being aware of the cancer.
- You may also get treatment although this was not really necessary. The treatment may cause various health problems. Some problems get better or disappear completely. Other problems may remain for the rest of your life. For example you may have problems getting an erection, leak urine or have looser stools.

APPENDIX 5

Standard algorithm for OPT 2026

The following algorithm follows essentially the National Healthcare Programme's recommendations (the differences are described in Appendix 6). The four regions within RCC North have a different diagnostic pathway: men with PSA above the threshold undergo a transrectal ultrasound and palpation of the prostate to select men for prostate MRI. Since 2026, men who have undergone prostate biopsy are transferred to another algorithm (on the right).





APPENDIX 6

Differences between the OPT recommendations and the National Healthcare Programme

The algorithm for OPT testing and diagnostics should, as far as possible, follow the recommendations in the National Healthcare Programme for prostate cancer, but some differences are motivated. One thing that separates OPT from ordinary clinical activities is that the diagnostics is based on a strict algorithm with binary outcomes that should allow minimal room for individualisation. Another difference is that there are limited possibilities to explain the meaning of PSA levels and MRI findings. The standard algorithm for OPT differs from the one in the National Healthcare Programme in the following ways:

Action threshold for PSA: The National Healthcare Programme recommends the action threshold PSA 5 µg/L for men aged 70–80 years. Within OPT it is inappropriate to raise the threshold from 3 to 5 µg/L for an individual man between two samplings. Therefore, within OPT, the recommended threshold is PSA 3 µg/L until follow-up ends at age 74 years.

New PSA test before decision on referral to MRI: The National Healthcare Programme recommends that men with PSA 3.0–9.9 µg/L and benign palpation findings take a new PSA test before considering MRI. Within OPT the palpation findings are unknown. If a new PSA test were to be taken, it would be unclear which of the two elevated PSA levels should be used for calculation of the PSA density. It would also lead to a considerable increase in the workload for the central offices to administer repeated PSA testing. Finally it would be difficult to explain in a letter to the men what the variation in the PSA levels means, which could make the men choose to submit new PSA tests outside OPT. For these reasons, a follow-up PSA test before MRI is not recommended within OPT. However, since 2025 a new PSA test is recommended before considering biopsy within OPT.

Action threshold for PSA for men taking 5-alpha reductase inhibitors: The National Healthcare Programme recommends halved action thresholds for men taking 5-alpha reductase inhibitors. It is however unclear how information about medication with 5-alpha reductase inhibitors can be obtained in a safe way within OPT. Region Stockholm initially inquired about medication with 5-alpha reductase inhibitors in connection with blood sampling, but the information about medication was often incorrect, which resulted in unmotivated biopsies for some men. For this reason the same action threshold applies to all men, regardless of any medication with 5-alpha reductase inhibitors, since this information is missing.

Biopsy threshold for PSA density for PI-RADS 1–2: The National Healthcare Programme recommends systematic biopsies for PSA density ≥ 0.20 µg/L/cm^3. In 2023, the National OPT Working Group decided not to raise the threshold from 0.15 to 0.20 µg/L/cm^3 since a large part (15 %) of men in OPT with PI-RADS 1–2 and PSA in this interval had cancer with a Gleason score of 7. However, in 2024, Region Stockholm raised the threshold to 0.20 µg/L/cm^3 to compensate for the fact that their method of analysis yields somewhat higher PSA levels than the methods of the other regions.

Follow-up after benign biopsies: The procedures for repeated biopsies differ somewhat between regions. After the primary biopsy, possibly supplemented with another biopsy within OPT, the vast majority of patients are followed up within OPT with another PSA test after 2 years. Individualised follow-up should be avoided as far as possible; in cases where the OPT procedures clearly do not suit the individual patient, the OPT office should be contacted and the patient should be removed from OPT.

Indication for new MRI for PI-RADS 1–2: The National Healthcare Programme recommends that men who are being monitored for elevated PSA levels after a previous MRI with PI-RADS 1–3 and whose PSA density has increased by ≥ 0.05 µg/L/cm^3 from that level at MRI, should take another PSA test after 4 weeks. Within OPT, the recommendation since 2024 is no new MRI for men with a previous MRI during the last 3 years, and with PI-RADS 1–2 and a current PSA < 10 µg/L with PSA density < 0.1 µg/L/cm^3. Other men with PSA ≥ 3.0 µg/L are referred for another MRI within OPT.

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APPENDIX 7

Management of incidental findings in prostate MRI

Background

Men who participate in OPT and have PSA ≥ 3 µg/L shall, where possible, undergo prostate MRI. For many of these men, no suspicion of prostate cancer emerges; these men are offered a new test after 2 years without any personal contact with a doctor or nurse. Although prostate MRI is a targeted examination, it may yield incidental findings of varying severity. Since OPT specifically offers testing for prostate cancer to men without any known symptoms, it is important to as far as possible avoid unnecessary distress, investigation and follow-up of incidental findings that are of no significance for their health. At the same time, it may be difficult for radiologists and medical directors of OPT to assess which incidental findings are relevant to describe to the man, which should motivate initiatives for investigation and which should not even be mentioned in the report. The National OPT Working Group has developed the following guidelines for structured reporting and management of incidental findings.

Information about possible incidental findings to men in OPT

When men are informed that prostate MRI will be the next step in the investigation, they should also be informed that incidental findings that are considered to be of significance for their health will be communicated to them. The text should be the same in all regions: "Sometimes the examination shows something outside the prostate which may be of significance for your health. In this case we will contact you."

Radiological reporting of incidental findings

nly incidental findings that are considered to be of significance for the man's health should be stated in the report from prostate MRI. These findings have been defined previously, during the work with the standardised diagnostic templates on INCA. The National OPT Working Group agrees with this assessment, with a few specifying additions. The following incidental findings should be reported from prostate MRI within OPT:

- Suspected cancer
    - Alteration in the bladder which may indicate a tumour
    - Polyp or tumour in the rectum or sigmoid colon
    - Lymph node with suspected metastasis
    - Alteration in the bone marrow which may indicate metastasis
    - Other findings that may indicate cancer, e.g. a soft tissue tumour

- Other findings that clearly require action, for example
    - Ureteral stone
    - Bladder stone
    - Very large bladder volume indicating significant urinary retention

Examples of non-relevant incidental findings include arthrosis, fluid in the small pelvis, inguinal hernia, Spigelian hernia, ureterocele, bladder diverticula and sigmoid diverticula.

From 2026, the proportion of MRI examinations with reported incidental findings will be a quality indicator for OPT. The OPT offices report the type of incidental findings and whether they have led to any action to SweOPT.

Management of reported incidental findings

The medical director of each regional OPT office is responsible for the management of reported incidental findings. Exactly how this should be done is for each individual office to decide, but incidental findings that are considered to be of significance for the man's health should be stated in the medical record, as well as a plan for continued management of the incidental finding and communication with the patient.

Incidental findings that have been stated in the MRI report but are not considered to be of significance for the man's health, do not need to be stated in the medical record or communicated to the patient.

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