HEALTH SYSTEMS AND POLICY ANALYSIS

POLICY BRIEF 83

Innovations in population-based cancer screening programmes

Key considerations for effective implementation

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Key messages

Cancer screening can reduce cancer morbidity and mortality by identifying early abnormalities, before they cause signs and symptoms.

Organized, population-based screening delivers higher quality outcomes than opportunistic testing, because it is systematic, quality-assured and offers more equitable access and coordinated pathways to cancer detection and care.

Cancer screening programmes optimize their full potential when they achieve high uptake in the population, particularly among high-risk groups, and are able to deliver fast, accurate cancer detection services.

Given the above, the European Union is encouraging Member States to consider **three innovations with potential to transform cancer screening pathways**:

a) self-administered testing

b) risk-based stratification

c) artificial intelligence (AI)-aided reading of radiological imaging.

Current knowledge about these screening innovations stems largely from small scale analyses and more robust studies are needed. Nonetheless, implementation experiences so far have generated a number of key insights.

Self-administered testing improves screening access by shifting screening from clinics to people's homes – thus reducing time, travel and stigma-related barriers. Evidence shows that:

- Self-administered testing is effective for colorectal, cervical and gastric cancer screening;
- Direct mailing of test kits is effective in increasing uptake, particularly when combined with health professional-led outreach and education;
- Vulnerable populations require tailored community engagement to ensure equitable benefit.

Risk-based stratification improves screening efficiency by using individual risk profiles (including, for example, family or smoking history) to tailor screening eligibility, screening intervals and follow-up pathways.

- Risk stratification channels screening resources to those most likely to benefit and reduces screening-related harms in lower-risk groups; it is also expected to improve overall value for money.
- Risk prediction models (or risk calculators) can only achieve the above impacts if they include evidence-based risk factors and if they are validated in the populations and settings they are implemented in, to ensure accuracy and minimize bias.
- Given its involvement in preventive services, primary care is likely best placed to manage risk assessment and risk calculation, but needs to be supported by well-developed data infrastructures (such as electronic health records) and training for health professionals (particularly in risk interpretation and communication).

AI-assisted image reading shows promise in improving the accuracy and timeliness of cancer screening, compared to traditional computer-assisted detection (CAD) for lung and breast cancer.

- When used as a second reader of radiological imaging, AI can streamline screening workflows, reduce diagnostic delays and alleviate pressures on the health workforce.
- However, there are implementation challenges to the use of AI.
  - The availability of representative real-world datasets for validation and bias mitigation of AI tools and algorithms is limited.
  - Resources and tools to support clinician–patient communication about AI-aided clinical decisions are lacking.
  - Clinician training and co-creation are needed to ensure that AI tools are safe, ethical and acceptable.

Integrating cancer screening innovations into population-based programmes is important and more likely to succeed if policy-makers tackle cross-cutting concerns. Areas worth focusing on include:

- Encouraging screening uptake through:
  - Clear public health education and communication to build trust and improve participation;
  - Tailored approaches that fit the participants' circumstances and enable equitable access;
  - Compliance with ethical and governance frameworks to protect informed consent and privacy.
- Making implementation of innovations and change feasible in practice by:
  - Training health professionals to help innovations become part of routine practice;
  - Integrating innovations into existing screening and diagnostic workflows;
  - Maintaining human support and involvement to complement technological solutions;
  - Building robust data infrastructures to support validation, testing and implementation of technological innovations.
- Improving the evidence base on the effectiveness, implementation and cost-effectiveness of cancer screening innovations by:
  - Drawing on cancer screening programme monitoring and evaluation data;
  - Developing and supporting large, prospective, multi-country evaluations.

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AI	Artificial intelligence
CAD	computer-assisted detection
CSAW	Cohort of Screen-Aged Women
CUB	Collaborative User Board
EHDS	European Health Data Space
EU	European Union
FIT	Faecal immunochemical test
GDPR	General Data Protection Regulation
gFOBT	Guaiac faecal occult blood test
HPV	Human papillomavirus
H. pylori	*Helicobacter pylori*
LDCT	Low-dose computed tomography
ML	Machine learning
MRI	Magnetic resonance imaging
NCH-PT	National Cancer Hub of Portugal
NSS	National Screening Service
OECD	Organisation for Economic Co-operation and Development
PRS	Polygenic risk scores
PSA	Prostate-specific antigen
RCT	Randomized controlled trial
SAT	Stool antigen test
TLHC	Targeted Lung Health Check
UKLS	United Kingdom Lung Cancer Screening
WHO	World Health Organization

Executive summary

Improving cancer screening access, efficiency and timeliness: the need for innovations

Cancer screening is a cornerstone of European cancer control strategies, aiming to reduce cancer morbidity and mortality by identifying early abnormalities, before they cause signs and symptoms. Organized, population-based cancer screening programmes deliver consistently higher quality screening than opportunistic testing by promoting equitable access, systematic oversight, quality assurance and coordinated pathways across the cancer screening pathway. Such programmes have long been in place across the European Union (EU) countries for breast, cervical and colorectal cancers. Although cancer mortality rates have declined substantially due to advancements in cancer treatment and the introduction of cancer screening programmes, cancer remains a leading cause of death globally and in Europe, underlining the need to continue to improve and innovate cancer screening programmes.

Given the evolving knowledge about cancer risk factors and cancer detection technologies, the Council of the EU updated its cancer screening recommendations in 2022, urging Member States:

1. To continue to improve existing breast, cervical and colorectal cancer screening programmes;
2. To explore the feasibility of lung, prostate and gastric cancer screening programmes through targeted pilot and implementation studies.

The EU recommendations also identified key innovations that countries should consider implementing due to their significant potential to transform the screening pathways for multiple cancers. These innovations include:

1. Self-administered testing, to optimize access to screening;
2. Risk-based stratification of the target population, to optimize the efficiency of screening;
3. Artificial intelligence (AI)-aided reading of radiological imaging, to optimize the timeliness of cancer screening.

In order to enact the Council recommendations, countries need practical information about how to implement cancer screening innovations. By virtue of being innovations, the scientific evidence base about their implementation is emerging; however, since these innovations are at different implementation phases for different cancer sites, there is an opportunity to identify promising implementation strategies that could be transferable across cancer-specific screening programmes.

In this context, in this policy brief, we provide up-to-date evidence about the implementation of self-sampling, risk-stratified screening and AI-aided cancer screening, to help policy-makers and health care planners incorporate them into existing or new screening programmes.

Self-administered cancer screening tests: an innovation to increase screening coverage and uptake

Self-administered testing brings cancer screening from the clinic to the person's home. Currently, there are evidence-based self-administered test options available for colorectal cancer (faecal immunochemical test [FIT]), cervical cancer (vaginal swab for human papillomavirus [HPV]), and gastric cancer (stool antigen test [SAT] for Helicobacter pylori [H. pylori]). Direct mailing of test kits has been associated with higher screening uptake overall and among under-screened people than providing test kits at the participants' request. In-person kit distribution by health workers may be effective in communities with limited access to health care. Patient navigation, involving personalized support from community health workers, may increase both screening test completion and linkage to follow-up care (e.g. repeat screening at the next round or diagnostic investigations for abnormal test results). Educational support is needed to ensure that people understand sample collection and follow-up procedures. Care must be taken to minimize the environmental impact of unused self-sampling kits.

Risk stratification of the target population: an innovation to tailor screening protocols to those who benefit the most

Risk-stratified cancer screening segments the eligible population into multiple risk-based strata, each of which follows its own, risk-adapted screening pathway. Such an approach prioritizes screening resources for those most likely to benefit, which potentially reduces screening-related harms for those at lower risk and saves costs to the health care system. Several risk calculators have been developed for breast, colorectal, cervical, lung and prostate cancers, with pilot studies underway in many European countries. The choice of risk calculator is contingent on the setting where it will be implemented, including the suite of variables to be collected, the data sources used, the timing of data collection, and the threshold for defining risk groups and the resulting screening pathways. It is crucial that the risk calculator at hand is validated in the target population to ensure its accuracy and to limit its potential for bias. Risk-stratified screening introduces a new step into the cancer screening pathway: risk factor assessment (or risk calculation). Given their involvement in preventive care, primary care settings are likely best suited to implement risk calculation and manage risk assessment; however, this needs to be supported by well-developed data infrastructures (such as electronic health records). In addition, health professionals require training and support to accurately administer risk assessment to screening participants and to communicate the risk assessment results.

AI-aided radiological image reading: an innovation to streamline screening workflows

AI-aided reading of radiological imaging is a promising emerging alternative to traditional computer-assisted detection (CAD) for lung and breast cancer. In particular, using AI as a second reader in radiological image processing may alleviate health workforce constraints and streamline delay-prone screening workflows. Ensuring that radiologists are exposed to AI in their professional training – for instance, as part of initial qualification, continuing education and quality improvement initiatives – is important for clinicians to find AI tools acceptable. Involving clinicians in co-creation of AI tools may also facilitate the tools' adoption in clinical practice in ways that are ethical and safe. Health professional training should consider the unintended consequences of AI tool implementation, such as overreliance on AI outputs. Although most screening participants and patients are interested in understanding the role of AI in their care, there are few evidence-based communication strategies and aids to support clinicians in transparently discussing AI outputs with their patients as part of shared clinical decision-making. Explainable AI models are key to both facilitating AI tool adoption among clinicians and to communicating clinical findings to screening participants and patients. A key barrier to implementation remains the availability of few representative real-world datasets to support external validation of AI tools – which is needed to minimize bias in AI algorithms.

Implementing cancer screening innovations in the real world: cross-cutting considerations

A successful integration of cancer screening innovations into population-based programmes requires a consideration of the following cross-cutting issues.

- **Public health education and communication** about changes in screening protocols is necessary to ensure that the intended end-users of cancer screening – the screening participants – find innovations acceptable and trustworthy. To participate in cancer screening, people need to understand the value of cancer screening processes and pathways.
- **Health professional training** on innovative cancer screening approaches is needed to support clinicians in routinizing them in their practice and in communicating about them with the screening participants. It is important that training emphasize how innovations can complement, rather than replace, the work of health professionals.
- **Human support and engagement with technology-based innovations** is necessary to ensure that they are seamlessly integrated into existing screening programme workflows. Human support is needed to help distribute screening test kits, provide public health education and administer risk assessments. Screening participants are also more likely to have confidence in innovations when they know that a human element remains at the core of their care.
- **Personalizing cancer screening approaches** to the life circumstances and personal preferences of the screening participants is key to ensuring equitable access. Shifting care from the clinic to the community – for example, through self-administered tests and mobile health clinics – can increase screening coverage and uptake. Tailoring screening protocols based on risk can reduce the potential harms of screening procedures, improving their benefit.
- **Robust data infrastructures** are crucial to support the deployment of screening innovations, including cancer risk prediction and AI models. Importantly, the mathematical algorithms used in risk calculators and AI tools need to be rigorously tested and validated using representative datasets to ensure that they are unbiased and appropriate for their target populations.
- **Compliance with ethical and governance frameworks**, such as the General Data Protection Regulations (GDPR), is essential to maintain the principles of informed consent and privacy. There is inherent tension between algorithms requiring significant data input, and privacy rules and regulations. International standards are needed for responsible algorithm development.
- **Evaluations of implementation, feasibility and cost-effectiveness** are required to continue building the scientific evidence base. Much of the current knowledge about cancer screening innovations stems from small, lower-quality studies. Large, prospective, international studies are paramount for real-world implementation of cancer screening innovations.

Policy Brief

1. Why this brief?

Cancer screening is a cornerstone of European countries' cancer control strategies. Cancer screening aims to detect precursor or early-stage lesions in people that appear healthy, before signs and symptoms cause them to seek clinical care[1] (Wilson & Jungner, 1968; Eddy, 1986). This is because cancers identified in their precursor or early stages are more amenable to curative treatment, ultimately resulting in better survival (Wilson & Jungner, 1968; Eddy, 1986). For example, over 90% of people diagnosed with early-stage breast, cervical or colorectal cancers survive beyond 5 years after their diagnosis; on the other hand, fewer than 30% of those with late-stage diagnoses do so (De Angelis et al., 2017; Sant et al., 2015). Furthermore, the screening modalities used for cervical and colorectal cancer allow precursor lesions to be identified, and their surgical removal prevents some cancers from ever developing (IARC, 2019; IARC, 2022).

Population-based screening programmes for breast, cervical and colorectal cancers began rolling out in many countries between the 1960s and the early 2000s, propelled by advances in laboratory and imaging techniques for cancer screening and detection (American Cancer Society, 2021). Unlike opportunistic screening – where tests are administered ad-hoc during routine health care encounters – organized programmes involve coordinated, systematic activities across the cancer screening pathway, from invitation to screening, diagnosis and subsequent care (Sagan et al., 2020; WHO Regional Office for Europe, 2022; Zhang et al., 2022) (see **Box 1** on page 10 for an overview of key cancer screening concepts and definitions). Organized, population-based cancer screening programmes thus deliver consistently higher quality screening than opportunistic testing by promoting equitable access, systematic oversight, quality assurance and coordinated pathways to subsequent care (Gini et al., 2020; Jansen et al., 2020; Schüz et al., 2015; WHO Regional Office for Europe, 2022; Zielonke et al., 2020).

Although cancer mortality rates have declined substantially due, in part, to advancements in cancer treatments and the introduction of cancer screening programmes (American Cancer Society, 2021), cancer remains a leading cause of death globally and in Europe[2] (Bray et al., 2024). Moreover, continuous advances in knowledge of cancer risk factors (e.g. tobacco and nicotine use; HPV) and cancer detection technologies are also opening doors to more precise, accessible and acceptable screening approaches. There is therefore a need to continue to improve and innovate cancer screening programmes. Recognizing this, the Council of the EU updated its cancer screening recommendations in 2022 (European Parliament, 2022). Member States were urged to continue to improve existing breast, cervical and colorectal cancer screening programmes and to explore the feasibility of lung, prostate and gastric cancer screening programmes through targeted pilot and implementation studies (see **Table 1** on page 11 for a summary of the Council recommendations).

In particular, the 2022 Council recommendations specify two overarching priorities for innovation across cancer screening programmes to improve screening quality:[3]

1. Optimizing equitable **access** to screening through self-administered tests, such as the FIT for colorectal cancer screening, HPV self-sampling for cervical cancer screening, or the SAT for H. pylori screen-and-treat programmes for gastric cancer prevention;
2. Optimizing the **efficiency** of screening by selecting the target population that is more likely to benefit from screening according to each person's individual level of risk, rather than basing this on age and sex alone (whether for existing screening programmes for breast, cervical and colorectal cancer, or the forthcoming programmes for lung and prostate cancer).

1 It is important to draw a distinction between screening, early diagnosis and early detection. Pre-symptomatic detection is the goal of cancer screening programmes – in other words, screening works by sorting apparently healthy individuals into those who likely harbour cancer or precancerous changes (requiring further investigation) and those who likely do not. Early diagnosis is defined as early identification of cancer in people who already have symptoms of the disease (World Health Organization, 2017). The goal of early diagnosis services is thus to improve people's awareness of cancer signs and symptoms and to reduce barriers to timely diagnostic and treatment services. Early detection is an umbrella term, encompassing early identification of cancer in people with and without symptoms. Both cancer screening and early diagnosis are important but distinct components of overall cancer control strategies. In the context of this brief, when we refer to "early-stage cancers", we are referring to cancers that are expected to be detected through screening. We do not comment on innovations and services involved in early diagnosis.

2 When we refer to "Europe" or "European countries", we mean EU Member States. However, since we are focusing on innovative screening approaches, where relevant, we also draw on the scientific evidence from other high-income "peer" countries (defined as members of the Organisation for Economic Co-operation and Development [OECD] in this policy brief).

3 The World Health Organization (WHO) defines quality health services as health services that are effective, safe, people-centred, integrated, equitable, timely and efficient (World Health Organization, 2018). The innovations prioritized by the Council of the EU are intended to improve aspects of screening quality, including equitable access (i.e. ensuring that screening is available to the entire target population, regardless of personal characteristics or circumstances), efficiency (i.e. ensuring that screening maximizes health benefits, while minimizing harms), and timeliness (i.e. ensuring that screening does not delay the cancer detection and diagnosis process).

The Council also reviewed the evidence on some emerging cancer detection technologies,[4] such as AI-aided radiological imaging interpretation. While the Council concluded that this technology is not yet ready for full-scale roll-out, the 2022 report of the Scientific Advice Mechanism to the European Commission highlighted that:

3. AI-aided processing of radiological imaging for breast and lung cancer screening may improve the **timeliness** of cancer screening processes, and potentially address the problem of radiology specialists staffing shortages (Hesso et al., 2024; World Health Organization, 2020).

As countries seek to respond to Council recommendations, they are faced with major decisions on how to implement the recommended novel cancer screening approaches (henceforth referred to as "innovations") to reap their intended benefits. This policy brief focuses on three such innovations – self-administered testing, risk-stratified screening and AI-aided cancer screening – and provides policy-makers and health care planners with the current state of the evidence to support decisions on whether and how to bring them into existing or new screening programmes.

Box 1. Key cancer screening concepts and definitions

Population-based cancer screening (also termed "mass screening") refers to large-scale screening strategies that aim to improve cancer outcomes in a population (Wilson & Jungner, 1968; Eddy, 1986). As this involves administering potentially invasive and time- or resource-intensive examinations to a large asymptomatic group of people, most of whom do not have cancer, it is important to ensure that the benefits of mass screening outweigh its harms. Wilson and Jungner (1968) defined the conditions under which mass screening is appropriate.

- The cancer presents an important public health problem based on its prevalence and mortality in the population.
- The natural history of the cancer is reasonably well understood and has a recognizable asymptomatic stage.
- The prognosis of the cancer is correlated with cancer stages (such that a cancer detected at an asymptomatic stage confers better survival).
- Well performing, valid, effective and safe screening and diagnostic modalities, as supported by scientific evidence, are available for screening and early detection.
- Safe and effective treatment options exist for early-stage, screen-detected disease.
- Treatment yields more benefits for asymptomatic people with an early-stage, screen-detected diagnosis than for people presenting with signs and symptoms.

The **cancer screening pathway** outlines the health services involved throughout the screening process (WHO Regional Office for Europe, 2022) (as illustrated in **Figure 1** on page 12). Breakdowns along the cancer screening pathway (e.g. not receiving screening tests, screening results or referrals for follow-up of positive screening test results) reflect lower quality of screening, which could result in poorer cancer outcomes.

Organized cancer screening programmes coordinate health services across the cancer screening pathway with the ultimate objective of reducing cancer-specific mortality in a population. Organized cancer screening programmes have the following essential criteria[5] (WHO Regional Office for Europe, 2022).

- There is a documented policy to provide equitable, quality-assured screening, diagnostic and treatment services to the eligible population. The policy should also specify the governance, management and coordination mechanisms.
- The screening test is part of a pathway that includes further assessment of positive screening results and escalation to diagnosis and treatment services.
- The screening pathway is documented in written form and defined in accordance with evidence-based protocols and guidelines.
- The eligible population is defined according to the balance of benefits versus harms, as supported by the scientific evidence.
- The eligible population is invited and recalled for screening at regular, evidence-based intervals, using an invitation system.
- The diagnosis and treatment of screen-positive individuals is timely and evidence-based.
- There is a well-resourced quality assurance process to monitor and evaluate programme performance using valid, evidence-based indicators and standards.

Opportunistic cancer screening involves case-finding and administration of screening tests on an ad-hoc basis during routine health care visits (Miles et al., 2004; Gray et al., 2008). Although case-finding in some people with identified risk factors may be effective in the clinical context, it is unlikely to be beneficial at the population level. In fact, without a programme in place, indiscriminate population-wide screening may widen inequalities (as screening would be preferentially administered to those with greater health care access), increase harms (as quality assurance mechanisms may not be in place), and be potentially wasteful (as there may not be established mechanisms for referring individuals for follow-up investigations and treatment) (Sagan et al., 2020; WHO Regional Office for Europe, 2022).

4 In addition to AI-aided cancer screening, the Council reviewed the evidence on using blood- and tissue-based biomarkers in multi-cancer screening tests (Scientific Advice Mechanism to the European Commission, 2022). We have chosen to focus on AI technologies in this policy brief because they are already being implemented as part of the clinical workflow in some EU health care settings.

5 In practice, screening programmes vary widely in their ability to meet these criteria and therefore, in achieving organization. A recent international expert panel aimed to prioritize these criteria in order to move away from the organized/opportunistic binary and help programmes become "better organized". The following essential criteria had the highest level of expert agreement (90% or higher): (1) evidence-based guideline defining screening eligibility, screening processes, referral pathway and case management; (2) systems for identifying and inviting the target population; (3) policy framework defining the governance structure, financing and objectives of the screening programme; (4) quality assurance process to monitor and evaluate programme performance using appropriate indicators (Zhang et al., 2022).

Table 1. Summary of the 2022 Council of the EU cancer screening recommendations

CANCER SITE	SUMMARY OF RECOMMENDATIONS
Breast cancer	• Mammography screening for women[6] aged 50–69 continues to be recommended based on the European guidelines. • The Council suggests extending screening eligibility to women aged 45–74 years. • Risk-tailored screening may be considered for women with high breast density, detected on their first mammography (European Commission Initiative on Breast Cancer, 2024).
Cervical cancer	• Testing for HPV infection is the preferred screening test for women aged 30–65 years, using an interval of ≥5 years. • The Council suggests offering HPV self-sampling kits as an alternative to clinician-based sampling, particularly for non-responders to screening invitations. • The Council suggests adapting screening protocols (e.g. age eligibility, intervals) to individual risk levels, based on HPV vaccination status.
Colorectal cancer	• Self-administered FIT remains the preferred screening strategy for people aged 50–74 years, with colonoscopy as the follow-up test for those with positive screening results. • The Council suggests using FIT results for risk-tailored screening, by defining stool haemoglobin concentration thresholds based on sex, age and screening history.
Lung cancer	• The Council suggests implementing lung cancer screening programmes for current and former heavy smokers[7] using low-dose computed tomography (LDCT) as the primary test, where feasible. • These programmes should integrate lung cancer screening with smoking cessation services in high-risk individuals (current and former heavy smokers). • The Council suggests that systematic data-driven methods for identifying and reaching current and former heavy smokers are needed to ensure adequate screening programme uptake.
Prostate cancer	• The Council suggests implementing organized prostate cancer screening programmes where feasible, using the prostate-specific antigen (PSA) test as the primary screening test and magnetic resonance imaging (MRI) as a follow-up test. • Countries should ensure appropriate management and quality of care in men, considering individual cancer risk based on PSA and MRI findings.
Gastric cancer	• The Council suggests that countries and regions that have high gastric cancer incidence and mortality rates consider implementing screen-and-treat strategies for H. pylori, the principal gastric cancer risk factor. • There are three H. pylori screening tests whose use in screen-and-treat programmes is supported by the scientific evidence: the self-administered SAT, the urea breath test and the serology test (IARC, 2025).

Source: European Parliament, 2022, except as otherwise indicated.

6 In this policy brief, we use the words "man/men" and "woman/women" to refer to people's sex assigned at birth, recognizing that individual gender identity may differ and may affect sex-specific cancer screening.

7 Robust, randomized controlled trial (RCT) evidence has only demonstrated that lung cancer screening is effective at reducing mortality in current or former heavy smokers (de Koning et al., 2020; Jonas et al., 2021) – for this reason, screening is currently recommended in these groups. However, other factors, such as exposure to outdoor air pollution and second-hand smoke, have been identified as significant contributors to lung cancer burden (IARC, 2013; Turner et al., 2020). In addition, these risk factors may affect lung cancer risk differently in certain population subgroups, such as women, who are often underrepresented in clinical trials (Florez et al., 2024). As such, further research is needed to understand the implications of these risk factors for lung cancer screening in European settings (e.g. considering re-defining the screening eligibility criteria and the role of non-screening interventions, like air quality monitoring). The Council of the EU's recommendations suggest that in addition to smoking history, attention should be given to the identification and targeting of other high-risk profiles (European Parliament, 2022).

How is this brief structured?

This policy brief responds to the questions many policy-makers are confronted with as they consider how to act on the Council recommendations and implement the identified cancer screening innovations (namely, self-administered testing, risk-stratified screening and AI-aided cancer screening) within their population-based screening programmes.

1. Why are the identified screening innovations innovative, i.e. how do they add value to the cancer screening pathway?
2. How can the identified screening innovations be integrated into established cancer screening workflows, based on lessons from real-world experiences? What are the key implementation considerations?

As we are talking about innovations, the evidence base addressing these questions is still emerging; however, since these innovations are at different implementation phases for different cancer sites, there is an opportunity to identify promising implementation strategies that could be transferable across cancer-specific screening programmes.

In this context, this policy brief offers three deep-dive sections on the implementation considerations related to the three identified cancer screening innovations across the six priority cancers (that is, breast, cervical, colorectal, lung, prostate and gastric cancers), as applicable. The aim is to respond to the two above-mentioned questions to derive practical approaches for implementation and integration of one or more of these innovations within the established workflows of organized cancer screening programmes. To address these questions, we drew on the most recent scientific evidence and experiences from early adopters (**Box 2**).

Each of the three innovations can be expected to disrupt the cancer screening pathway as currently established (**Figure 1**). For instance, self-administered cancer screening largely changes the "testing" step in the pathway – specifically, the setting in which screening takes place.

Box 2. Methods for this policy brief

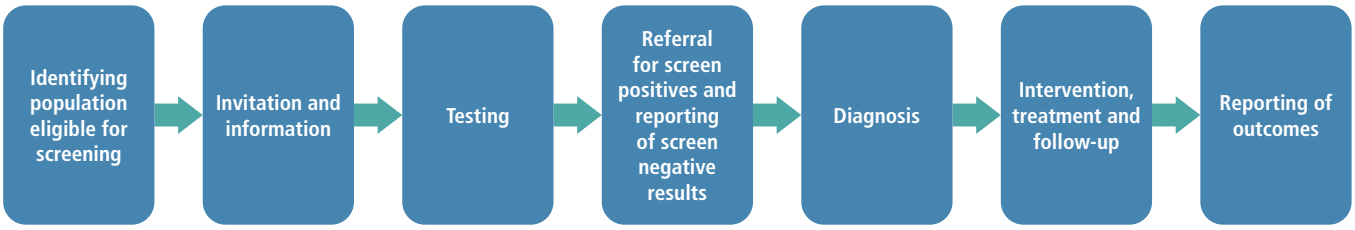
This policy brief draws on a rapid review of the literature and country case studies.

For the rapid review, two academic bibliographic databases (Medline and the Cochrane Library) were systematically searched in February 2025 using search terms related to cancers, screening, self-sampling, risk stratification and AI-aided cancer screening. The citations were screened in duplicate by two reviewers in two phases: titles/abstracts and full-text articles. Peer-reviewed studies were included if they discussed implementation of at least one of the three cancer screening innovations of interest (i.e. self-sampling, risk stratification, AI-aided screening) for at least one of the six priority cancers (i.e. breast, cervical, colorectal, lung, prostate, or gastric) in high-income settings (defined as OECD members). Studies considered to be more authoritative – for example, recent, well-conducted, comprehensive systematic reviews or other evidence syntheses – were prioritized for inclusion. Additional references were retrieved by searching Google Scholar, forward and backward citations, the authors' records, and through expert consultations. Findings were collated in accordance with the two key questions guiding this review.

Countries identified as early adopters of the cancer screening innovations of interest (e.g. through their participation in EU-wide cancer screening initiatives, like MyPeBS for risk-stratified breast cancer screening [see **Box 8**, page 22]) were selected for illustrative case studies of implementation. The case studies were then developed using the literature retrieved in the rapid review and through engagement of experts working in country-specific cancer screening research and practice.

AI-aided reading of radiological imaging alters the "diagnosis" step – in other words, how cancer imaging is processed. Risk-stratified screening arguably transforms the screening pathway in the most substantial way, as it segments the identified eligible population into multiple risk-based strata, each of which has its own pathway – from invitation, through to testing (and re-testing on subsequent screening rounds), and follow-up for positive screening results (**Figure 2**, page 13). In addition, the implementation of some form of risk-stratified screening is applicable to most of the priority cancers (i.e. breast, cervical, colorectal, lung and prostate cancers).[8]

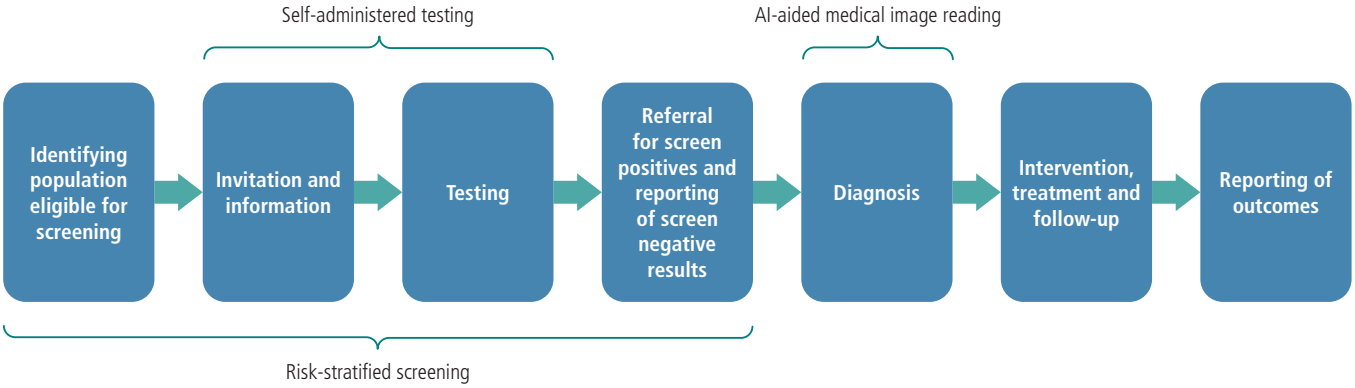
Figure 1. The cancer screening pathway



Source: Adapted from WHO Regional Office for Europe, 2022.

8 European efforts for gastric cancer prevention currently focus on population-based H. pylori screen-and-treat strategies in high-incidence areas (European Parliament, 2022; IARC, 2025). Key ongoing EU-funded projects, such as TOGAS and EU-GAINS, aim to inform the development and implementation of H. pylori screen-and-treat programmes in Europe, including screening protocols, modalities and quality assurance standards. Further risk stratification is not yet being considered in the gastric cancer prevention context and is thus not discussed in this brief.

Figure 2. Cancer screening innovations in the context of the cancer screening pathway



Source: Adapted from WHO Regional Office for Europe, 2022.

For this reason, we devote more space in this brief to risk stratification compared to the other two innovations, to be able to synthesize the full breadth of the evidence base.

In the following sections, we look at each innovation in turn: self-administered testing (Section 2); risk-stratified screening (Section 3); AI-aided medical image reading (Section 4). In the first subsection for each innovation-specific deep dive, the innovations are analysed in terms of the first of the two above-mentioned key questions, i.e. their added value to established cancer screening processes – that is, what makes these innovations innovative. In the second subsection of each deep dive, we discuss the second key question, i.e. the practical ways in which they can be embedded within the screening pathway. Section 5 of the brief then considers cross-cutting considerations for implementing all three innovations. Lastly, Section 6 concludes the brief with the way forward. Throughout the brief, we provide illustrative case studies of notable country experiences with implementation.

2. Self-sampling as an innovative testing approach to improve screening access

2.1 Why is self-administered cancer screening innovative?

Cancer screening programmes can only optimize their impacts if they achieve high coverage (defined as the number of people eligible for screening who are able to access screening) and uptake (defined as the number of eligible people who actually get screened). In other words, programmes that are able to reach much of their target population are expected to decrease late-stage diagnoses (when cancers are less treatable) and ultimately, reduce cancer morbidity and mortality (Wilson & Jungner, 1968; WHO Regional Office for Europe, 2022).

Self-administered cancer screening tests

Traditionally, cancer screening tests have been administered by health care providers during clinic visits. Self-administered cancer screening tests (also referred to as "self-sampling", "self-collection", or "home-based testing") are tests that can be used by screening participants for self-examination at home, without the direct supervision of health care personnel[9] (World Health Organization, 2023). Self-administered cancer screening tests thus bypass the need for clinic visits, thereby allowing both the general population and those with limited health care access to receive cancer screening services more easily. This way, self-sampling exemplifies an innovation with the power to transform screening coverage and uptake across colorectal, cervical and gastric cancers. Currently, the Council of the EU's recommendations include the following self-administered cancer screening tests: FIT (colorectal cancer), HPV self-sampling (cervical cancer) and SAT for *H. pylori* detection (gastric cancer).

Colorectal cancer

Self-administered stool-based testing has been part of the standard of care for colorectal cancer screening over the past two decades, first through the guaiac faecal occult blood test (gFOBT) and more recently through the FIT (IARC, 2019). Both tests detect the presence of blood in the stool, which may be indicative of precancerous or cancerous polyps in the colon or rectum that require further investigation (IARC, 2019).

The FIT is considered to be superior to the gFOBT due to its higher sensitivity[10] for detecting advanced polyps or cancer and its specificity to human haemoglobin (IARC, 2019; Schreuders et al., 2015; Lee et al., 2014). These features make it a more user-friendly test for screening participants, as, unlike the gFOBT, the FIT requires the collection of only one stool sample and does not involve pre-collection dietary restrictions (IARC, 2019; Schreuders et al., 2015). RCTs showed that the use of the FIT increased screening uptake by 21% compared to the use of the gFOBT (Vart et al., 2012). In this light, most European countries with organized colorectal cancer screening programmes that previously used the gFOBT as their first-line screening test began to switch to the FIT after 2014 (IARC, 2019; Schreuders et al., 2015). In many settings, the switch to the FIT narrowed participation gaps across age, sex and socioeconomic groups (Digby et al., 2013; Moss et al., 2017). Yet despite reducing disparities, few EU countries have attained the 65% uptake benchmark set by the Council, leaving the potential gains afforded by the FIT unrealized (Ola et al., 2024).

Cervical cancer

For cervical cancer screening, self-administered testing emerged as an innovative alternative to clinician-based testing more recently. Originally, cervical cancer screening was done through cervical cytology tests, which involved an examination of the cervix for early abnormalities that may later become cancerous. Human papillomavirus testing became the preferred first-line cervical cancer screening approach after HPV was established to be the primary cause for most cervical cancers (IARC, 2022). Many European countries have been gradually transitioning to HPV testing over cytological testing since 2016 (IARC, 2022). Although both cervical cytology and HPV testing are performed by a health care provider in a clinic during a pelvic exam, the transition to HPV testing has opened the opportunity to introduce self-sampling as an alternative option, whereby women can collect a vaginal sample at home. Many cervical cancer screening programmes are now rolling out HPV self-sampling as a screening option for women who have never engaged with clinic-based cytology (Arbyn et al., 2021; Serrano et al., 2022). Early data from Netherlands (Kingdom of the)[11] and Sweden reveal that most self-sampling participants have never been screened before, underscoring its promise for boosting overall coverage and uptake (Aitken et al., 2023; Arroyo Mühr et al., 2024).

9 In this section, we focus on self-administered tests that have been included in the Council recommendations and thus have the potential for implementation. It is of note that there are other emerging technologies that may fall under the self-administered testing umbrella, including the collection of menstrual blood for HPV testing and the use of smart toilets for detecting occult blood. These modalities may further reduce some barriers associated with self-collection, such as discomfort and embarrassment. However, the evidence base does not currently support their implementation. To date, some studies (outside the European setting) have shown that HPV can be reliably detected in menstrual blood (Tian et al., 2026), but robust evaluations are needed to compare this method of collection to existing screening protocols. The utility of smart toilets in the colorectal cancer screening setting is largely only theorized (Ge et al., 2023).

10 Sensitivity is the ability of a screening test to accurately identify all people that have a health condition. Specificity is the ability of a screening test to accurately rule out the presence of a health condition (i.e. identify all people that do not have a health condition).

11 Note that Netherlands (Kingdom of the) comprises six overseas countries and territories and the European mainland area. As data for this Report refers only to the latter, the Report refers to it as the Netherlands throughout.

In meta-analyses of diagnostic accuracy studies, HPV self-sampling was shown to have comparable sensitivity and specificity for detecting cervical lesions to clinician-based sampling (when polymerase chain reaction amplification is used) (Arbyn et al., 2018; Arbyn et al., 2022). Another meta-analysis showed that linkage to follow-up care in women with positive HPV tests was similar between self-samplers and physician-screened women (Yeh et al., 2019). The WHO recently included HPV self-sampling among its recommended evidence-based self-care interventions for health and well-being (WHO, 2023).

Gastric cancer

H. pylori screen-and-treat programmes for gastric cancer prevention involve testing for the presence of H. pylori infection and, in the case of a positive result, providing H. pylori eradication therapy. Recently, an IARC working group concluded that there are three tests whose use in H. pylori screen-and-treat strategies is supported by scientific evidence (whether individually or in tandem): the SAT, the urea breath test and the serology test (IARC, 2025).

The SAT is the only H. pylori screening test that is self-administered and is also the least invasive, which may yield higher uptake; however, this comes at the cost of a decrement in its performance for detecting H. pylori infection relative to the other test options (IARC, 2025). Yet, a key issue for consideration is that stool-based tests like the SAT may be combined with established FIT-based colorectal cancer screening programmes, enabling more efficient use of screening infrastructures (e.g. to invite the target population and to distribute test kits) (IARC, 2025). Currently, there are no population-based gastric cancer prevention programmes in Europe, and the choice of screening protocol and modality is highly dependent on features of the local context (IARC, 2025). Pilots of H. pylori screen-and-treat protocols using different test modalities are currently ongoing in real-world settings. These local evaluations will inform scalable strategies to reduce gastric cancer risk through broad population coverage (IARC, 2025).

Overall, self-administered cancer screening is innovative because it redefines where screening takes place – shifting it from the clinic to the comfort of people's homes. By simplifying processes, reducing barriers and enabling greater reach into under-screened populations, self-administered cancer screening has the potential to increase equity, autonomy and uptake. Self-administered tests can thus represent a paradigm shift in cancer screening if screening programmes are able to successfully embed them into screening pathways, as discussed next.

2.2 How can self-administered cancer screening tests be implemented in screening programmes to improve access?

When implementing self-administered cancer screening tests within screening programmes, one of the most fundamental strategic decisions is whether to adopt an opt-out or opt-in test kit distribution approach. In **opt-out** strategies (often also called "mail-to-all"), screening kits are proactively mailed to eligible individuals, usually with prepaid return envelopes. In **opt-in** strategies, individuals receive an invitation to request a screening kit (e.g. via telephone, mail or website), which may then be mailed to their home or picked up from designated locations, such as pharmacies or health centres.

Opt-out test kit distribution strategies significantly boost screening uptake over opt-in approaches, but require careful oversight

Opt-out strategies have consistently shown higher participation rates in both colorectal and cervical cancer screening programmes – a key consideration for policy-makers deciding how to design invitation systems. For example, a study in Ireland's organized colorectal cancer programme found that directly mailing FIT kits helped achieve national screening uptake benchmarks (see **Box 3**, page 16). Systematic reviews of RCTs in Europe and the United States of America found that mailed FIT kits increased screening uptake by a median of 22% compared to usual care (Issaka et al., 2019). Among underserved populations – such as immigrants, uninsured individuals and people with low income – mailed kits were associated with more than double the screening completion rate compared to usual care (Rubin et al., 2023; Belon et al., 2024).

The Netherlands offers a unique real-world example where both opt-in and opt-out strategies for HPV self-sampling have been attempted (see **Box 4**, page 16). Meta-analyses show that opt-out strategies roughly double cervical cancer screening attendance compared to opt-in strategies or usual care across both general and under-screened populations (Arbyn et al., 2018; Costa et al., 2023; Di Gennaro et al., 2022; Wong & Wong, 2024; Yeh et al., 2019).

Despite the clear impact on uptake, choosing an opt-out approach requires policy-makers to weigh several **cost-effectiveness and operational considerations** – many of which are still being evaluated in ongoing studies. Economic analyses of RCT data showed that mailed FIT kits have lower per-patient costs than colonoscopy invitations (Kapinos et al., 2022) or opt-in FIT strategies (Somsouk et al., 2020). For cervical cancer screening, a recent systematic review of modelling and RCT data showed that both opt-out and opt-in approaches to HPV self-sampling can be cost-effective, depending on willingness-to-pay thresholds (Hallson et al., 2026). Although opt-in approaches may be less costly than opt-out approaches due to fewer unused screening kits, this is often counteracted by lower screening uptake and thus, lower population benefit (Hallson et al., 2026).

Box 3. Direct mailing of FIT kits holds promise for increasing colorectal cancer screening uptake in Ireland

Despite being a well-established national programme, uptake in Ireland's organized colorectal cancer screening initiative, BowelScreen, remains suboptimal. Between 2022 and 2023, only 46% of the invited population completed and returned a FIT, falling short of both national and EU benchmarks (National Screening Service, 2025).

BowelScreen is overseen by the National Screening Service (NSS) and targets individuals aged 59–69 years, inviting them (via a mailed letter) to undergo FIT-based screening every 2 years. The list of eligible individuals is compiled using data from the Department of Social Protection, with options for self-registration available online or via telephone.

Currently, an opt-in approach is used, whereby first-time invitees to screening must actively request a FIT kit by contacting a call centre. If there is no response to the initial invitation, a reminder letter is sent after 8 weeks. To address low screening uptake, the programme has been exploring alternative invitation and reminder strategies.

A recent quasi-experimental study (Clarke et al., 2025) tested two interventions among first-time BowelScreen invitees who did not respond to the initial invitation:

1. An opt-out approach, with direct mailing of FIT kits to participants' homes;
2. A modified reminder letter incorporating behavioural science-informed messaging to address common barriers to screening.

In May 2022, 8424 individuals were invited to undergo screening, and 7718 (92% of those invited) non-responders to the initial screening invitation were included in the study. These non-responders received one of four intervention combinations: the standard screening reminder letter, the standard reminder letter with an enclosed FIT kit, the modified reminder letter, or the modified reminder letter with an enclosed FIT kit. FIT completion was assessed 3 months later.

The results showed that enclosing a FIT kit in either type of reminder letter (opt-out approach) led to a 6% increase in uptake compared to the standard reminder letter, which is the current usual care (54% vs 48%). After adjusting for sex and socioeconomic status, individuals who received a FIT kit with their reminder letter had 26% to 30% higher odds of returning a completed test, compared to those who had to request a FIT via the call centre (opt-in approach). However, the modified reminder letter alone did not significantly impact uptake, suggesting that behavioural messaging may need to be tailored to specific subgroups with distinct barriers to screening.

While direct mailing of FIT kits helped achieve the national benchmark of 50% uptake, it still fell short of the EU-recommended 65%. This raises questions about whether a broader opt-out approach – mailing FIT kits to all eligible individuals with the first invitation (rather than the reminder letter) – could further improve participation. The effectiveness and cost-effectiveness of such an approach remain to be studied.

In practice, screening programmes must continuously monitor uptake, explore reasons for non-participation, and test and refine programme components based on their country context. Learning from other countries' experiences, adapting interventions to local populations and programme features, and iteratively improving implementation are key to increasing screening uptake and maximizing public health impact.

Box 4. Comparison of opt-out and opt-in strategies for distributing HPV self-sampling test kits in the Netherlands

Cervical cancer screening remains essential – even in populations with access to HPV vaccination. In the Netherlands, national HPV vaccination coverage among age-eligible women was 55% in 2023 (van Lonkhuijzen et al., 2025). A recent study showed that 15% of Dutch women diagnosed with cervical cancer had previously been vaccinated (van Lonkhuijzen et al., 2025). This finding underscores the continued importance of screening as a complementary strategy to vaccination in cervical cancer prevention.

The Dutch cervical cancer screening programme stands out for its early adoption of HPV self-sampling and its shift towards an opt-out approach. The Netherlands was the first EU country to implement nationwide cervical cancer screening using HPV as the primary test in 2017 (IARC, 2022). While most countries offer HPV self-sampling only to under-screened women (Serrano et al., 2022), the Dutch programme makes self-sampling universally available as an alternative to clinician-based sampling.

The programme is coordinated by regional screening organizations and is overseen by the National Institute of Public Health and Environment (RIVM), which mails invitation letters to eligible women. Initially, an opt-in strategy was used for self-sampling, requiring women to request a free kit after receiving an invitation or reminder letter (IARC, 2022). Uptake was low – only 7% of invited women chose self-sampling in the first 2 years – but the method showed considerable promise for underserved groups, including never-screened women, those in the youngest and oldest age groups, unemployed individuals and those living alone, as they were over-represented in that 7% (Aitken et al., 2023).

Due to the COVID-19 pandemic, the number of women choosing HPV self-sampling more than doubled in 2020 (Arbyn et al., 2023). Building on evidence from trials showing that mailing self-sampling kits directly to women (opt-out strategy) improves uptake, the RIVM adopted an opt-out approach in 2021 (Arbyn et al., 2023). Under the current protocol:

- Newly eligible 30-year-old women receive HPV self-sampling kits with their first invitation letter.
- Other eligible women receive a kit if they do not respond to the initial invitation after 12 weeks.

The impact of the opt-out strategy on screening uptake, disparities and cost-effectiveness remains to be quantified, but the Dutch experience offers valuable insights into how screening programmes can evolve with emerging evidence.

Another key issue is environmental impact: unused kits that are not returned contribute to waste and may limit cost-efficiency (Scientific Advice Mechanism to the European Commission, 2022). Improper self-administration of screening kits is similarly wasteful, as it precludes them from being processed and interpreted. There is also the risk of double screening, particularly for cervical cancer, where both self- and clinician-administered screening options may be available simultaneously. Screening programmes must avoid duplication, which offers no clinical benefit and wastes resources (Lozar et al., 2021). Ultimately, decisions regarding the test kit distribution strategy (opt-in vs opt-out) and the target population (all individuals eligible for screening vs non-responders or those newly eligible) must be based on the local context, considering expected uptake, resource constraints and programme goals.

In-person kit distribution delivers major gains in screening uptake, especially for hard-to-reach groups, but requires strategic investment in community-based models

For policy-makers looking to improve screening uptake, in-person distribution of self-sampling kits represents a **high-impact but resource-intensive strategy** that can be targeted to populations least reached by standard invitation methods. It is particularly effective when integrated with broader community engagement activities. For example, **community health workers, allied health professionals and patient navigators** can play a crucial role in targeted distribution of in-person test kits, especially in hard-to-reach groups. They often have trusted relationships in communities and can help bridge barriers to screening.

Meta-analyses show that door-to-door or community-based distribution of HPV self-sampling kits more than doubles participation compared to usual care (Di Gennaro et al., 2022; Yeh et al., 2019). Community-based distribution venues – such as pharmacies, shopping, community and fitness centres, or religious institutions – can reach populations such as recent immigrants or residents of rural and remote areas (Fullerton et al., 2024).

For colorectal cancer, in-person distribution of FIT kits has resulted in completion rates between 71% and 90% in populations with limited access to care (Belon et al., 2024). Distributing FIT kits during preventive care visits, such as mammography appointments or flu vaccination clinics, also improves screening rates (Issaka et al., 2019; Belon et al., 2024). Completed kits may be either collected by the community health workers in person or mailed by the participants via prepaid envelopes, with both strategies having similar effects on return rates in cervical and colorectal cancer screening (Belon et al., 2024; Yeh et al., 2019). An EU-funded pilot (TOGAS[12]) is currently assessing whether H. pylori screening for gastric cancer prevention can be implemented alongside FIT-based screening for colorectal cancer (IARC, 2025).

Crucially, the effectiveness of in-person distribution depends on **strong interpersonal interaction, culturally tailored communication and community trust**, all of which policy-makers must factor into programme design, workforce planning and budgeting. The success of pharmacy-based engagement in the Portuguese Azores illustrates how sustained local relationships can drive high participation in screening initiatives (see **Box 5**, page 18). Designing effective policy pathways therefore requires not only weighing cost and workforce implications, but also recognizing that community-embedded delivery models may be essential for achieving equitable screening coverage.

Clear communication and efforts to improve health education are critical for safe, successful self-sampling

Regardless of the screening test kit distribution strategy, **health promotion and education** are especially crucial in the self-sampling context, where people are expected to self-administer health examinations without health professional assistance. These should be viewed as core programme components and not optional add-ons. While many people prefer self-sampling due to convenience and privacy (Aimagambetova et al., 2024; Ali et al., 2023; Colonetti et al., 2024; Fullerton et al., 2024; Nishimura et al., 2021; Tatara et al., 2022), a number of challenges limit uptake and proper use (Aimagambetova et al., 2024; Ali et al., 2023; Chand et al., 2023; Fullerton et al., 2024; Honein-AbouHaidar et al., 2016; Hu et al., 2023; Nishimura et al., 2021; Tatara et al., 2022).

Common barriers to self-administration of cancer screening tests include:

- Lack of awareness of the need for screening while feeling "healthy" or being asymptomatic;
- Difficulty understanding written instructions related to test self-administration (particularly if not accompanied by clear visual illustrations);
- Perceived or actual inability to self-administer the test correctly;
- Discomfort with sample handling (e.g. during self-administration or when returning the kit for processing);
- Misconceptions about the accuracy of self-administered tests, relative to those administered by health professionals.

To address these challenges, policy decisions that prioritize investment in communication strategies that support safe and equitable self-sampling are important – strategies such as using clear, illustrated instructions, providing reassurance about test accuracy, explaining the importance of screening and what to expect after test completion (Belon et al., 2024; Chand et al., 2023; Tatara et al., 2022).

12 https://www.togas.lu.lv/ (accessed 16 July 2026).

Box 5. A community pharmacy-driven approach for SAT kit distribution achieved a high uptake of H. pylori screening in Portugal

Portugal has one of the highest gastric cancer incidence and mortality rates in western Europe (Morais et al., 2016; Peleteiro et al., 2014). H. pylori is estimated to affect about 60–80% of the Portuguese population (Peleteiro et al., 2015). There is substantial variation in both gastric cancer incidence and H. pylori prevalence across the country, likely due to differences in population density and socioeconomic position (Morais et al., 2016; Peleteiro et al., 2014; Peleteiro et al., 2015).

In March 2024, the National Cancer Hub of Portugal (NCH-PT) announced the launch of a pilot population-based H. pylori screen-and-treat programme for gastric cancer prevention (SAPO 24, 2024; Diário Dos Açores, 2024). The pilot was developed by the NCH-PT Prevention Working Group, a multidisciplinary group with representatives from academia, health care units, the national pharmacy association and patient and professional organizations.

The first phase of the pilot took place in Terceira – an island in the Azores archipelago with approximately 50 000 inhabitants, where the incidence of gastric cancer exceeds the national average (Forjaz, 2018). The short-term aim of this pilot was to estimate the prevalence of asymptomatic H. pylori infection in Terceira and screening adherence rates, to ultimately inform wider programme implementation. The long-term goals of the project are to assess whether a population-based H. pylori screen-and-treat strategy will significantly reduce the incidence of gastric cancer.

For this pilot, the SAT was selected as the principal screening modality due to its similarity to colorectal cancer screening, which already has a population-based organized screening programme in the Azores. However, while colorectal cancer screening test kits are usually mailed to people aged 50–74 years, SAT kits for H. pylori screening were provided to all adults (aged ≥18 years) self-presenting to local pharmacies (SAPO 24, 2024). Local pharmacies were chosen to distribute SAT kits because they are likely to capture a more diverse population than that seen in health care settings. A public health media campaign, using local and national newspapers, televised news and social media, accompanied the pilot programme launch to inform the public about the relevance of screening, screening eligibility, and the process for obtaining and completing a screening kit.

Completed SAT kits were returned by participants to the local pharmacies and sent on to the hospital laboratory for analysis (SAPO 24, 2024; Diário Dos Açores, 2024). Participants with negative SAT results were notified via text message, whereas those with positive results were contacted by telephone. Individuals who tested positive for H. pylori were invited for a medical consultation, during which they were prescribed an antibiotic regimen for eradication therapy (SAPO 24, 2024; Diário Dos Açores, 2024).

The initial phase of the pilot H. pylori screen-and-treat initiative, concluded in December 2024, achieved high uptake. Overall, 2000 test kits were made available for distribution and 1887 (94%) of them were obtained by participants who intended to use them. Of these, 1761 (93%) were completed and returned to pharmacies. Considering the 1006 people aged 50–74 years (the colorectal cancer screening target group), 949 returned a completed SAT between March and December 2024, representing an uptake rate of 94%. For comparison, over the same period, 3947 of 5,377 age-eligible individuals invited for colorectal cancer screening returned a completed test, representing an uptake rate of 73%.

The engagement of the local pharmacy network was key in enhancing H. pylori screening uptake. The interpersonal nature of pharmacist–community interactions, supported by pre-existing trust and familiarity, was instrumental in encouraging individuals to acquire and complete the screening kit. Based on the outcomes of this pilot initiative, the pharmacy-driven approach to test kit distribution may represent a scalable and effective model for implementation in other cancer screening programmes in the Azores based on self-sampling, including those for colorectal and cervical cancer.

Patient navigators and screening reminder systems can help promote uptake and follow-up, especially for vulnerable groups

Patient navigators – either allied health professionals or trained peer educators – are another effective mechanism for improving screening uptake and follow-up throughout the screening pathway. They can facilitate distribution of self-sampling test kits, alongside providing reminders about screening, appointment scheduling, linkage to follow-up care in case of positive or indeterminate screening results, language interpretation services, other barrier management, and health education (Nelson et al., 2025; Nelson et al., 2019; Belon et al., 2024; Budde et al., 2022; Bush et al., 2018; Raich et al., 2012; Rubin et al., 2023). Patient navigators can be particularly effective at improving access to screening and follow-up among people with socioeconomic barriers to care (Nelson et al., 2025; Belon et al., 2024).

Reminder systems following the distribution of FIT or HPV self-sampling kits are also beneficial. Studies show that live telephone calls are generally more effective than letters, automated calls or text messages (Belon et al., 2024; Fullerton et al., 2024; Issaka et al., 2019; Rubin et al., 2023). Motivational messaging (informed by behavioural science techniques) has shown mixed results but may offer additional value in low-income or rural populations (Belon et al., 2024).

3. Moving towards targeted risk stratification to improve efficiency

3.1 Why is risk-stratified cancer screening innovative?

Traditionally, cancer screening programmes have defined their target "average-risk" populations using broad age and sex criteria. Since age is one of the strongest predictors of cancer risk, this approach has proven effective at the population level. However, such an approach is also relatively crude in precision: actual cancer risk varies considerably according to a person's genetics, physical characteristics, personal and family health history, lifestyle, and exposure to environmental pathogens. As a result, the benefits of screening are not evenly distributed across the population.

Like any health intervention, cancer screening carries potential harms, which also vary at the individual level (Scientific Advice Mechanism to the European Commission, 2022). These include:

- False positives, leading to unnecessary invasive follow-up investigations (e.g. a false positive FIT prompting a colonoscopy);
- Overdiagnosis and overtreatment, particularly for lesions unlikely to progress or affect lifespan (e.g. older men undergoing aggressive prostate cancer treatment for indolent tumours);
- Direct procedural harms, such as bowel perforation during colonoscopy;
- Psychological harms, including stress and anxiety from receiving positive screening results and experiencing additional investigations or related complications.

Although clinicians discuss suitability for screening with their patients based on the possible benefits and harms, this process is largely subjective and inconsistent. Most average-risk guidelines still lack a quantifiable, standardized approach for weighing benefits against harms when considering whether to recommend screening (Zeng et al., 2020).

Risk-stratified cancer screening seeks to personalize screening recommendations – including screening eligibility, frequency and method – to an individual's calculated cancer risk (Scientific Advice Mechanism to the European Commission, 2022). This shift is innovative for two reasons:

1. **Targeting those most likely to benefit**: resources can be prioritized for people at higher cancer risk, improving the impact of screening.
2. **Reducing harm for those at lower risk**: those unlikely to benefit from more intensive screening can avoid unnecessary procedures and their associated risks.

At the population level, risk-stratified cancer screening is expected to be more cost-effective and efficient, as it involves focusing screening resources on higher-yield cases. At the individual level, personalized risk knowledge may empower informed decision-making, encourage healthy behaviour change and prompt preventive interventions for those at very high risk (e.g. hormonal therapy for breast cancer prevention).

Moving from a blunt (average-risk categories) to a precise (personalized multivariable risk modelling) risk stratification approach is expected to improve screening efficiency

The EU Council recommends exploring risk-tailored screening protocols[13] for breast, colorectal, cervical, lung and prostate cancers. Advances in data science and research on cancer risk factors have made it possible to develop multivariable risk models (also called "risk calculators" or "risk prediction models") that combine information on multiple risk factors, beyond age and sex, to estimate a person's probability of developing cancer over a defined time period. Examples of such advances include:

- **Breast cancer**: The transition to digital mammography has enabled measurement of breast density (one of the strongest breast cancer risk factors), improving risk estimation when included in risk calculators, particularly with data from multiple screening rounds (Anandarajah et al., 2023; Clift et al., 2022; Pashayan et al., 2020).
- **Colorectal cancer**: The increasing adoption of quantitative FIT[14] has permitted the measurement of haemoglobin concentration in the stool, which correlates strongly with cancer risk. Incorporating FIT results from previous screening rounds into risk calculators improves prediction accuracy (Cairns et al., 2022; Hull et al., 2020; Lansdorp-Vogelaar et al., 2022).

13 Some degree of risk stratification already exists in cancer screening: for example, people with significant family histories or known genetic risks of breast or colorectal cancer are recommended to start screening earlier and more intensively (NHS England, 2025; Cancer Research UK, 2024). However, multivariable risk calculators allow further precision, accommodating a greater number of significant risk factors alongside family/genetic risk.

14 FITs work by detecting the human haemoglobin concentration in the stool. Qualitative FITs only return binary findings (i.e. positive or negative). Positivity thresholds are typically set by manufacturers and thus can vary across devices (Tinmouth et al., 2015). In contrast, quantitative FITs return a numerical value for the concentration of human haemoglobin in the stool. This allows screening programmes to set their own positivity thresholds, thus enabling greater standardization. Since cancer risk is correlated with haemoglobin concentration, even those with sub-threshold (or negative) test findings can have meaningful cancer risk when other risk factors and the results of previous screening rounds are considered (Lansdorp-Vogelaar et al., 2022). For this reason, using quantitative FIT results in risk calculators can facilitate better personalization of screening protocols.

- **Cervical cancer**: The transition to HPV testing has enabled HPV genotyping, which identifies different HPV strains or subtypes that have been linked to different levels of risk. Risk calculators can tailor screening based on HPV subtype (based on previous screening rounds), as well as HPV vaccination status (Perkins et al., 2020; RISCC, 2025; Simoens et al., 2024).
- **Lung cancer**: The inclusion of health and socioeconomic factors in lung cancer risk calculators, rather than age and smoking history alone, has improved the identification of people who are likely to develop lung cancer, while reducing overdiagnosis (Baldwin et al., 2023; Tammemagi et al., 2022).
- **Prostate cancer**: Advances in PSA test interpretation have improved the ability of screening results to differentiate between clinically significant and insignificant cancers (i.e. those requiring more vs less intensive clinical management), reducing overdiagnosis (Louie et al., 2015; Van Poppel et al., 2021). Different PSA-thresholds are currently being explored for personalized screening protocols (see case study in **Box 6**).

Polygenic risk scores (PRS) represent another advancement in cancer risk estimation. These scores quantify how a person's unique genetic profile predisposes them to cancer (Dannhauser et al., 2024). The inclusion of PRS scores improves the performance of some risk calculators for breast (Clift et al., 2022; Pashayan et al., 2020) and colorectal (Cairns et al., 2022; Hull et al., 2020; Lansdorp-Vogelaar et al., 2022) cancers. However, there are many limitations that preclude broad use of PRS-based risk calculators. Estimating people's PRS requires widespread access to genetic testing; however, population-level genetic testing may be prohibitive due to substantial implementation costs and limited evidence to support the feasibility of these tests in healthy individuals (McElwee et al., 2026; Zhang et al., 2019).There is also substantial variability in PRS estimation methods and poorer predictive performance in non-European populations (Clift et al., 2022; Hurson et al., 2021; Pashayan et al., 2020; Sassano et al., 2022).

Box 6. Irish pilot of risk-stratified prostate cancer screening will inform screening strategies in Europe

Ireland has one of the highest incidence rates of prostate cancer in the EU, primarily attributed to high levels of opportunistic PSA screening, which is typically initiated during a general health check as part of a laboratory test panel (Burns et al., 2012a; Burns et al., 2012b; Maguire et al., 2025). It is likely that some of these cancer cases represent overdiagnosis – for instance, although Northern Ireland (United Kingdom) has lower rates of PSA testing and prostate biopsies, the prostate cancer mortality rates are similar between the two countries (Carsin et al., 2010). This suggests that a better alignment between prostate cancer risk and screening approaches is needed to avoid subjecting people to unnecessary procedures.

Ireland is part of the ongoing Prostate Cancer Awareness and Initiative for Screening Europe (PRAISE-U) project (detailed in **Box 8** on page 22), aiming to derive an optimal risk-stratified prostate cancer screening approach for European countries. Ireland is the only PRAISE-U pilot site to employ a self-administered PSA test, which will enable the simultaneous evaluation of self-administered testing and risk-stratified screening. The Irish pilot commenced in March 2025, led by University College Dublin and supported by the NSS and other partners (Smith, 2025).

A Collaborative User Board (CUB), composed of clinicians, screening participants, cancer patients and decision-makers, was engaged to ensure that the pilot programme is acceptable. The role of the CUB is to assess and address barriers to implementation, as supported through evidence gathered via focus groups and surveys with relevant stakeholders (Chandran et al., 2024).

In the Irish pilot, a randomly-selected sample of men (derived using a population-based NSS listing) was mailed invitations to participate (Chandran et al., 2024). Participants were asked to register online to be sent a free home-based finger-prick PSA testing kit. Participants would then post the completed kit to the study laboratory for analysis, and they would later be informed of their PSA test results online. The study uses the following risk stratification approach, developed in line with the Council of the EU and the European Association of Urology recommendations (Chandran et al., 2024; Van Poppel et al., 2021).

- Those with a PSA result of <1 ng/mg are recommended to re-screen every 5 years.
- Those with a PSA result of 1–3 ng/mg are recommended to re-screen every 2 years.
- Those with a PSA result of >3 ng/mg are referred for MRI for further classification into low, intermediate and high risk categories:
  - Those deemed low risk are re-screened after 2 years.
  - Those deemed intermediate or high risk undergo a prostate biopsy, the results of which indicate "no cancer" (re-screened after 2 years), "low risk" (active surveillance), or "high risk" (treatment).

As of March 2026, 1613 men had been recruited into the pilot (15% of the recruitment target), 13% had abnormal PSA results, 22% were classified as low risk, and 36% avoided biopsy (European Association of Urology, 2026; van Harten et al., 2026). These early findings suggest that risk-stratified prostate cancer screening holds promise for reducing unnecessary investigative procedures. Considering the low participation rate, future priorities for the PRAISE-U project include improving screening uptake rates, refining risk stratification algorithms based on local population characteristics, and expanding data collection through prospective registries to support further evaluations (including cost-effectiveness) (European Association of Urology, 2026).

Risk prediction models show promise – but real-world validation and standards are still lacking

Many models for breast (Clift et al., 2022; Meads et al., 2012; Pashayan et al., 2020), cervical (Jha et al., 2023), colorectal (Cairns et al., 2022; Hull et al., 2020; Wang et al., 2021; Lansdorp-Vogelaar et al., 2022), lung (Baldwin et al., 2023; Toumazis et al., 2020), and prostate (Louie et al., 2015; Van Poppel et al., 2021) cancers show reasonable predictive performance (see **Box 7** for an overview of key terms in model validation). Yet:

- This evidence is often based on modelling or small diagnostic studies, not large-scale real-world trials (Bandala-Jacques et al., 2021; Cairns et al., 2022; Clift et al., 2022; Hull et al., 2020; Kates et al., 2021; Lansdorp-Vogelaar et al., 2022);
- Despite substantial variation in model inputs and methodologies, no single "best" model exists, as there is no established benchmark for optimal performance (Bandala-Jacques et al., 2021; Cairns et al., 2022; Clift et al., 2022; Hull et al., 2020; Kates et al., 2021; Lansdorp-Vogelaar et al., 2022;
- External validation of models remains limited due to limited availability of external datasets (Dixon et al., 2022; Pashayan et al., 2018; Toumazis et al., 2023; Wang et al., 2022);
- Cost-effectiveness evidence, though favourable, largely comes from modelling, which relies on various assumptions and hypothetical scenarios, rather than real-world costing and outcome data (Dixon et al., 2022; Khan et al., 2021; Pashayan et al., 2018; Toumazis et al., 2023; Wang et al., 2022).

Real-world pilots and EU trials will determine how risk-stratified screening can work at scale

When policy-makers consider which risk calculator to implement and locally adapt, the following aspects will need to be considered (McWilliams et al., 2022):

- The time frame for risk estimation (e.g. 5-year vs lifetime risk);
- The type of outcome predicted (e.g. diagnosis, interval cancer or mortality);
- The trade-off between model accuracy and feasibility (e.g. whether to include PRS-based models, requiring widespread genetic testing, which is costly);
- Thresholds for defining risk groups and the resulting screening pathways.

However, as one of the essential elements of effective organized programmes is evidence-based definition of the target population (WHO Regional Office for Europe, 2022), large-scale implementation of risk calculators should be informed by real-world evaluation. Indeed, the impact of risk-stratified screening depends on programme organization, public acceptance and integration into clinical practice. Recent NHS England pilots like PROCAS (Evans et al., 2012) and BC-Predict (Evans et al., 2023) have demonstrated the feasibility and acceptability of risk-stratified breast cancer screening in a single setting. Large, multi-country trials are now underway in the EU to test real-world effectiveness, cost-effectiveness and feasibility of risk-stratified screening for multiple cancer types (see **Box 8** on page 22). These projects are expected to be completed between 2024 and 2028[15] and their findings will inform the development of adaptable guidelines and implementation toolkits, ensuring country-specific population characteristics are considered in risk-stratified screening approaches.

Box 7. Key concepts and terms in mathematical model validation

Since the distribution of risk factors, and therefore cancer risk, varies substantially across different populations, the performance of any chosen model must be established in each relevant population through a process called **model validation** (Hull et al., 2020).

Model performance depends on how strongly the set of characteristics (or risk factors) included in it predict cancer risk (or probability); this will affect how well the model is able to discriminate between people that will be diagnosed with cancer vs those that will not.

Internal validation establishes the performance of the model using the data from the population in which it was developed in. For example, a dataset could be randomly split in half, with one half being used to generate the model (i.e. select the set of risk factors to be included in it) and the other half being used to validate it (i.e. check how well the model distinguishes between people that do and do not develop cancer).

External validation establishes the performance of the model in another population. Specifically, a model that was generated and internally validated in one dataset is deployed in a different dataset, sourced from another population, to check how well the model estimates cancer risk in an external group of people.

15 Large-scale evidence-based guidelines and implementation toolkits are typically developed using structured expert validation and consensus methods, which may take 12–24 months to complete (NICE, 2025). As such, while the results of the real-world studies are forthcoming, their interpretation and operationalization into actionable country-level guidance will require further inputs and longer timelines.

Box 8. Key EU-funded multi-country real-world studies of risk-stratified cancer screening

MyPeBS (My Personal Breast Cancer Screening)[16] is a multi-centre randomized clinical study aiming to assess the effectiveness and feasibility of risk-stratified breast cancer screening, relative to the standard of care. The project was launched in 2019 in Belgium, France, Italy, the Netherlands, Spain and the United Kingdom, and is expected to be completed in 2027. Women aged 40–70 years are randomized to standard screening based on the national guidelines or to the risk-stratified group. Five-year breast cancer risk is assessed using the following variables: age, family history, previous history of benign breast biopsy, personal hormonal and reproductive history, mammographic breast density and PRS. The proprietary Mammorisk risk model is used for women with no or one first-degree relative with breast or ovarian cancer and the Tyrer-Cuzick risk model is used for women with two or more first-degree relatives with breast or ovarian cancer.

ONCOSCREEN[17] is a project aiming to develop a risk-based, population-level stratification methodology for colorectal cancer screening. The project began in 2023 and is expected to conclude in 2026. The project is led by a multidisciplinary, multi-stakeholder consortium of 38 partners, with representation from Austria, Belgium, Bulgaria, Cyprus, France, Germany, Greece, Ireland, Israel, Italy, Lithuania, the Netherlands, Portugal, Romania and Spain. The project work packages focus on developing novel, practical, low-cost and high-performing screening technologies, leveraging AI to develop personalized risk stratification, and providing a mobile app to enable colorectal cancer risk awareness and self-monitoring. The anticipated risk stratification model will account for genetic, socioeconomic and environmental variables associated with the risk of different onsets of the disease.

PRAISE-U (PRostate cancer Awareness and Initiative for Screening EUrope)[18] is a pilot project aiming to derive and evaluate a risk-stratified population-based prostate cancer screening algorithm to be implemented in organized screening programmes, in place of the current opportunistic screening. The project was launched in 2025, with pilot sites in Ireland, Lithuania, Poland, Spain (Galicia and Manresa regions), and is expected to be completed in 2028. The pilot sites differ in the features of their screening programmes and the study screening algorithm has been adapted to each setting. Risk stratification is based on the Rotterdam Prostate Cancer Risk Calculator, which uses information on PSA levels, history of prostate biopsy and digital rectal examination, and prostate volume estimation to predict the risk of detecting clinically significant prostate cancer (Chandran et al., 2024).

RISCC (Risk-based Screening for Cervical Cancer)[19] is a project aiming to improve the quality of cervical cancer screening by developing an evidence-based and validated risk-stratified cervical cancer screening programme and open-source mobile and digital implementation tools. The project started in 2020 and was concluded at the end of 2024. The project was led by a consortium of 11 partners, representing health care, academic, research and professional organizations from Belgium, Finland, Italy, the Netherlands, Slovenia, Spain and Sweden. In February 2025, the RISCC consortium published its guidance document, outlining its evidence-based recommendations for risk-stratified cervical cancer screening – including the role of HPV genotyping and HPV vaccination status in screening (RISCC, 2025). A proof-of-concept study of risk-stratified screening was conducted in Sweden using the following variables from the national registry data to define high-risk groups: age, HPV genotype, long-term non-attendance at screening, and history of cytological abnormalities on prior screening rounds (Arroyo Mühr et al., 2024).

SOLACE (Strengthening the screening of Lung Cancer in Europe)[20] is a project aiming to inform the implementation of lung cancer screening programmes across the EU. The project was launched in 2023 and is expected to conclude in 2026. The project consortium is led jointly by the European Society of Radiology and the European Respiratory Society, with 37 partners from academic, health care, research, and patient and professional organizations from 15 EU countries. The project work packages include developing consolidated evidence-based guidelines, implementing pilot studies targeting previously under-represented groups in lung cancer screening (e.g. women, socially disadvantaged groups, ethnic minorities, residents of remote regions), and monitoring long-term impacts and sustainability. Among the current or forthcoming lung cancer screening programmes participating in SOLACE that use risk stratification, the $PLCO_{m2012}$ risk model is applied to define screening eligibility (Kauczor et al., 2024). This model assesses 6-year lung cancer risk using age, race or ethnicity, education, body-mass index, history of chronic obstructive pulmonary disease, personal history of cancer, family history of lung cancer, and current or previous smoking intensity (Tannemagi et al., 2022).

16 https://www.mypebs.eu/ (accessed 16 July 2026).

17 https://oncoscreen.health/ (accessed 16 July 2026).

18 https://uroweb.org/praise-u (accessed 16 July 2026).

19 https://www.riscc-h2020.eu/ (accessed 16 July 2026).

20 https://europeanlung.org/solace/ (accessed 16 July 2026).

3.2 How can risk-stratified cancer screening be implemented within screening programmes to improve screening efficiency?

Risk-stratified screening adds complexity – with operational choices ultimately shaping success and equity

Risk-stratified cancer screening adds additional steps to the traditional cancer screening pathway (as illustrated in **Figure 3**), including:

- assessing individual risk
- stratifying people into different risk groups
- communicating risk assessment results
- offering risk-tailored screening protocols, based on the assigned risk group (Pashayan et al., 2020).

While this approach promises more precise targeting of screening eligibility and better use of resources, it also brings a series of operational decisions that screening programmes must address during implementation. Experience from research studies and pilot programmes shows that these decisions carry major implications for feasibility, equity and public trust.

Where to locate risk assessment – primary care, remotely or in the community?

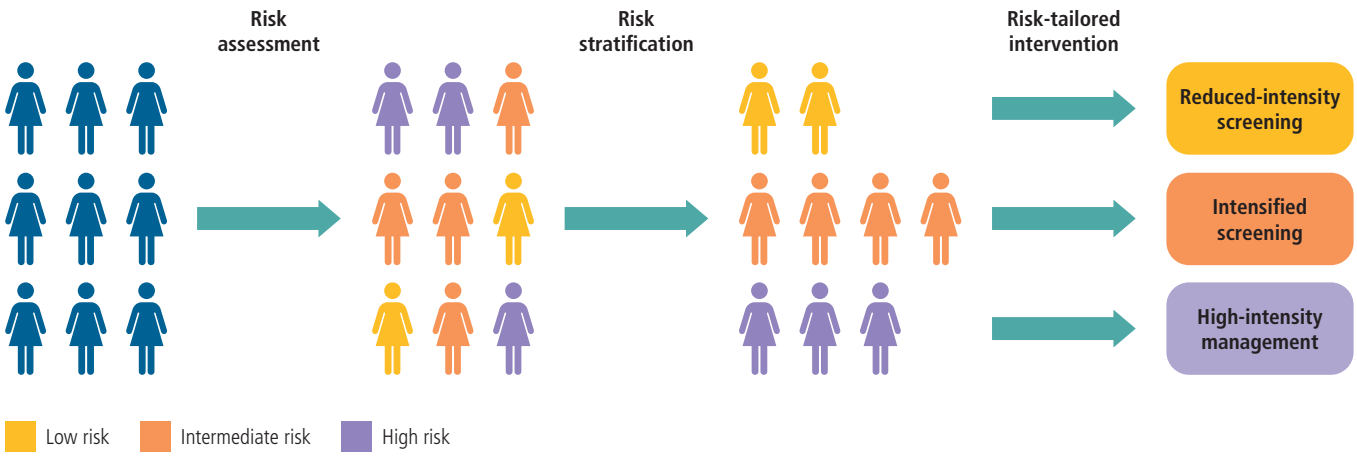
One of the first questions is where the risk assessment should actually take place. While there is no single agreed-upon setting, primary care and general practice emerge as logical options, given their existing relationships with patients, collection of risk factor data through medical records, and experience in managing chronic disease preventive services (Dunlop et al., 2024; McWilliams et al., 2022). In particular, primary care systems with high levels of population-based patient registration – whereby patients are formally attached to a specific primary care practice or provider – may be more ready to implement risk-stratified cancer screening. This is because continuous registration may enable better collection of complete and accurate longitudinal risk factor data in medical records. For example, in the United Kingdom, where patient registration is mandatory, primary care electronic health records have high completeness of quality-assured demographic, testing, diagnostic, therapeutic, lifestyle and referral data (Herrett et al., 2015; Thiru et al., 2003).

In the absence of well-resourced primary care health record infrastructures, risk factor data may be recorded by health professionals during designated appointments. However, in many health systems, the short length of routine consultations makes it difficult to conduct a thorough cancer risk assessment (Dunlop et al., 2024; Tan et al., 2025). To overcome this, some screening programmes have tested alternative approaches. Having patients complete risk assessments remotely before an appointment – either in a waiting room or by telephone – has been shown to be more manageable within time constraints (Dannhauser et al., 2024; Dunlop et al., 2024). Bringing the service into the community can also be an effective strategy, especially among underserved populations. One part of the pilot phase of NHS England's lung cancer screening programme, for example, targeted socially disadvantaged areas and offered point-of-care risk assessments in mobile LDCT vehicles stationed in shopping centre car parks. This was met with strong interest from the community (see **Box 9** on page 24).

Who performs risk assessments matters for feasibility and trust

The choice of a risk assessor is closely tied to the setting. General practitioners (or family physicians) and nurses are trusted and credible, but their capacity is often stretched (Dunlop et al., 2024). In both clinical and non-clinical settings, dedicated non-clinical staff such as patient navigators or community health workers, trained in cancer risk counselling and risk communication, have been effective at engaging participants (Dunlop et al., 2024; Scientific Advice Mechanism to the European Commission, 2022). What is essential – regardless of setting – is that participants view the risk assessor as having the right training and expertise to discuss cancer risk (Dunlop et al., 2024).

Figure 3. Schematic of risk-stratified cancer screening



Source: Adapted from Pashayan et al., 2020.

Box 9. Implementation of risk-stratified lung cancer screening in United Kingdom (England) prioritized areas with the lowest socioeconomic status

The United Kingdom Lung Cancer Screening (UKLS) pilot trial, conducted in Liverpool and Cambridge between 2010 and 2015, aimed to build on previous seminal trials (the United States National Lung Cancer Screening trial and the Dutch-Belgian NELSON trial) by introducing a risk model that considered other variables to determine individual cancer risk, beyond smoking history and age (Field et al., 2016). This approach was selected to avoid the inclusion of individuals at very low risk of lung cancer to improve detection rates and inform health economic analyses. In the UKLS, people aged 50–75 years were considered eligible for LDCT screening if their 5-year risk of lung cancer exceeded 5%, as determined by their smoking duration, history of respiratory disease and cancer, family history of lung cancer, and occupational exposure to asbestos (the Liverpool Lung Project model). The trial found that 86% of lung cancers could be detected at an early stage, before they showed symptoms. Economic modelling using trial data suggested that this intervention could be cost-effective, although long-term mortality data would be required to confirm this.

Subsequent community-based pilot studies were conducted between 2015 and 2018 in Manchester, Liverpool and north London in areas of high lung cancer incidence, which corresponded to areas with a high proportion of people experiencing socioeconomic disadvantage (Crosbie et al., 2018; Ghimire et al., 2019). Manchester and London introduced the concept of a one-stop "lung health check", where age-eligible ever-smokers were assessed for their lung cancer risk, invited to undergo LDCT screening if they met the risk threshold, and provided with smoking cessation advice (Crosbie et al., 2018; Ruparel et al., 2020). A key feature of the Manchester pilot was that people were approached in community settings, such as local shopping centres, and screening was offered immediately in mobile screening vehicles. The community approach aimed to reduce barriers to participation among people with lower socioeconomic status, who were more likely to smoke and have a greater lung cancer risk. The Manchester pilot used the $PLCO_{m2012}$ model – which estimates risk using both health and socioeconomic status-related factors (Tammemagi et al., 2013; Tammemagi et al., 2022) – to define screening eligibility, with those having a 6-year lung cancer risk of over 1.5% being included. These community-based pilots achieved similar results to the UKLS, with 80% of cancers detected at an early stage. The pilots also demonstrated that people with lower socioeconomic status are interested in lung cancer screening, with the majority of those approached consenting to participate and 75% of them being ranked in the lowest socioeconomic quintile.

Influenced by the mounting international evidence, the intention to increase the early-stage detection rate for all cancers, and the results of the UKLS and community-based pilots, NHS England began rolling out what became known as the Targeted Lung Health Check (TLHC) programme in 2019, prioritizing the most deprived areas (Smith, 2024). Overall, by March 2025, the programme had offered screening eligibility assessments to 32% of the estimated potentially eligible population in England, with over 2.5 million people invited to undergo a lung cancer risk assessment and over 7000 lung cancers diagnosed (75% at stages I or II). Notably, as a result of the programme, people living in the most deprived areas were shown to be more likely to be diagnosed with lung cancer at an earlier stage than people in less deprived areas. While approximately 70% of screening took place in mobile screening units, the programme was also delivered in secondary care settings, with smoking history data from electronic medical records being used to identify potentially eligible individuals. In 2023, following a positive recommendation from the UK National Screening Committee, the British government announced that the TLHC would be scaled up into a national lung cancer screening programme. The programme is expected to achieve full national coverage of the eligible population by 2029.

Integrating risk tools into workflows is key; digital solutions can streamline but need standardization

The delivery mode refers to how the risk assessment tool is integrated into existing systems. Many health care providers prefer to see calculators integrated into electronic medical records, as this streamlines workflow and supports automatic data capture (Dannhauser et al., 2024; Dunlop et al., 2024). Yet many general practice information technology systems are not designed to handle tailored invitation and recall processes for multiple risk groups (Dunlop et al., 2024).

One way around this is a pre-screening step: a simplified model applied to existing records to identify a smaller pool of people for full risk assessment (Baldwin et al., 2023). Some programmes incorporate risk assessment into the screening invitation process. For instance, the first Swedish lung cancer screening pilot mailed invitations to age-eligible women on the breast cancer screening register; a QR code and web link included in the invitation gave access to an online risk assessment questionnaire, with immediate confirmation of screening eligibility (Martin-Moreno et al., 2025). Similarly, the BC-Predict study in England (United Kingdom) sent women a second letter, alongside their routine mammography invitation, directing them to an online risk assessment platform, while also offering the option to complete it in person at the mammography appointment (Evans et al., 2023).

Publicly available web-based tools, such as the Rotterdam Prostate Cancer Risk Calculator app or the American Society for Colposcopy and Cervical Pathology guidelines app, can be useful, but differences in methodology can lead to widely varying risk estimates for the same person (Kates et al., 2021). Screening programmes may therefore prefer to recommend and standardize specific web-based tools to ensure consistency.

Timing matters: when and how often to assess risk shapes precision and resource use

When to assess risk depends largely on what information the chosen model requires. Models relying on self-reported factors – such as family history or lifestyle – can be applied at the first screening round. Some models require variables that only become available after an initial test, such as mammographic breast density, FIT haemoglobin concentration, HPV genotype or PSA levels. A hybrid approach may be considered, where a quick first-round risk assessment is used to identify higher-risk individuals that can be immediately stratified into intensive screening protocols. Risk estimates for the remaining participants can then be refined once information from first-round screening is available (McWilliams et al., 2022).

Timing is not just about the first assessment. Risk factors change over a person's lifetime, and repeated measurements can improve model performance – for example, multiple breast density readings are more predictive of cancer risk

than a single one (Anandarajah et al., 2023; McWilliams et al., 2022). Programmes must thus decide how often to reassess cancer risk and be prepared to reallocate participants to risk-tailored screening pathways accordingly.

Choosing the right data source is about balancing feasibility and accuracy

Data for risk assessment can come from self-reporting, clinician collection or electronic medical records – each with their own trade-offs. Self-reporting is inexpensive and easy to scale, but suffers from recall bias, especially for complex factors like family history (Dunlop et al., 2024; Hull et al., 2020). Clinician-collected data and medical record documentation are generally more accurate than self-reporting, but can vary in completeness across practices – particularly for lifestyle risk factors (Dunlop et al., 2024; Thiru et al., 2003). A mixed approach, supported by quality standards for electronic medical record entries, may give the best balance between feasibility and validity.

Clear, tailored communication is fundamental to building trust and ensuring adherence to risk-based screening

Calculating a person's cancer risk is only useful if they understand it and know what it means for their care. Studies show that while most people find risk-stratified cancer screening acceptable (Dannhauser et al., 2024; Dunlop et al., 2024; Tan et al., 2025), this does not always translate into following the recommended screening protocol (Dannhauser et al., 2024; Tan et al., 2025). Barriers include confusion about how risk is calculated, particularly when PRS are involved, anxiety about the implications of what the estimated cancer risk means for themselves and their families, and concerns about data privacy (Dannhauser et al., 2024; Dunlop et al., 2024; Kates et al., 2021).

There is also a common scepticism among low-risk individuals about reducing screening intensity, with some suspecting a cost-cutting motive (Dunlop et al., 2024; Tan et al., 2025). Evidence suggests that trust increases when people are given clear explanations of risk factors, the process of calculating scores, and the evidence base for different screening intervals (Dunlop et al., 2024). Communication methods can be tailored – for example, text messages or letters for low-risk participants, in-person or video consultations for high-risk (Dunlop et al., 2024) – but some studies find an overall preference for face-to-face discussion (Dannhauser et al., 2024).

Health professional training in risk stratification is an essential component of safe, effective implementation of risk-stratified screening

Delivering risk-stratified screening requires new skills, and providers themselves recognize this. Around 86% of health care providers agree that risk-stratified cancer screening is appropriate, but 96% say they need more training before they can integrate it into practice (Tan et al., 2025). Training priorities include understanding the clinical utility and limitations of risk-stratified models compared to average-risk guidelines, the specific challenges of PRS interpretation (especially given their lower accuracy in non-European ancestry groups), and the legal, social and ethical implications of personalized risk pathways (Dannhauser et al., 2024; Dunlop et al., 2024). Continuing professional education, updated in line with emerging evidence and guidelines, is important, as is familiarity with public-facing web-based tools, so that providers can answer questions and address discrepancies in risk assessment findings (Dunlop et al., 2024; Dannhauser et al., 2024; Kates et al., 2021). Point-of-care decision support tools may also help in explaining results to screening participants (Dunlop et al., 2024).

4. AI-aided cancer screening to improve workflow timeliness

4.1 Why is AI-aided cancer screening innovative?

Delays in cancer diagnosis and subsequent treatment are recognized as contributing to poor outcomes in many EU countries (Hesso et al., 2023; Hesso et al., 2024). These delays are partly driven by the persisting shortages in the health workforce, particularly among radiologists (Hesso et al., 2024; World Health Organization, 2020) – a problem likely to worsen as lung cancer screening programmes are rolled out and as mammography services expand to younger age groups, thus increasing the populations eligible for screening. Against this backdrop, AI-aided cancer screening is emerging as an innovation with considerable potential to improve the timeliness of screening services and to address workforce capacity constraints (Brady et al., 2024; Hesso et al., 2023).

Policy-makers and practitioners are increasingly confronted with the role of AI within health care systems and processes. AI-aided radiological image interpretation in **lung and breast cancer screening**[21] is being viewed as the logical next step after CAD. CAD systems have long been part of radiological image interpretation workflows (Brady et al., 2024; Geppert et al., 2024; Rangayyan et al., 2007), with early CAD systems having been shown to improve the accuracy of radiologist image interpretation (Rangayyan et al., 2007). A typical CAD session involves a first image reading by a radiologist, followed by an image review by the CAD software, which highlights any suspicious features for further consideration (Rangayyan et al., 2007).

Image interpretation is inherently complex, requiring accurate pattern recognition and classification of abnormalities. Errors in image interpretation can take the form of false positives, leading to unnecessary interventions, or false negatives, resulting in missed diagnoses (Rangayyan et al., 2007). Interpretation accuracy is affected by radiologist expertise, workload and the high imaging volumes generated by screening programmes. To reduce misclassification, the EU quality assurance guidelines recommend double reading: having two independent radiologists review each image (von Karsa et al., 2013). However, evidence suggests that the second reader may only marginally improve cancer detection rates (Dinnes et al., 2001) and that double reading may not be cost-effective (Posso et al., 2016), especially in the context of workforce burnout (Liu et al., 2024) and variability in clinical recommendations between radiologists (Cochon et al., 2019).

AI, particularly systems based on machine learning (ML), offers a potential solution to these challenges. Increasingly, AI systems are being recognized for their potential in improving the accuracy and efficiency of multiple components of the radiological imaging workflow[22] (Brady et al., 2024; Kapoor et al., 2020). Unlike traditional CAD systems, which rely on predefined rules and thresholds, ML algorithms learn directly from raw images to identify features relevant to classification (Brady et al., 2024; Geppert et al., 2024; Nagendran et al., 2020). This capability raises the possibility that AI may detect subtle patterns not readily apparent to the human eye, thereby improving both accuracy and timeliness of image interpretation (Nagendran et al., 2020; Noguerol et al., 2019).

Evidence to date suggests that AI can function effectively as a second reader in radiological image interpretation workflows. In lung cancer screening, a systematic review found that AI-aided radiologists achieved faster LDCT reading times per patient case and higher sensitivity in detecting and categorizing lung nodules compared to unaided radiologists, although specificity was reduced (Geppert et al., 2024). In mammography, systematic reviews show that AI assistance can increase cancer detection rates without extending reading time (Anderson et al., 2022; Rentiya et al., 2024). The AI-aided single-reader strategy – combining human expertise with AI support – has been found to be the most acceptable to both health care professionals and patients, as it preserves human involvement while reducing the image processing turnaround times (Hesso et al., 2023; Pesapane et al., 2024; Woode et al., 2025).

Despite these promising findings, resourcing high-quality datasets (i.e. those representative of real-world screening populations, with diverse patient demographics, tumour types, and balanced representation of normal and abnormal findings) is needed to address significant limitations in the AI space.

- Most evidence comes from diagnostic accuracy studies using retrospectively collected data, with relatively few prospective studies or trials (Anderson et al., 2022; Geppert et al., 2024; Nagendran et al., 2020; Rentiya et al., 2024).

21 In this brief, we focus on AI applications to radiological imaging – specifically, mammography (for breast cancer) and LDCT scans (for lung cancer) – as this was the focus of the Council of the EU's evidence review and recommendations. These tests are used as primary screening modalities for the respective cancers and are thus directly relevant to cancer screening. That said, it is worth noting that applications of AI technologies are also being actively researched in cancer diagnostic modalities outside the scope of radiology, including AI-guided endoscopy or colonoscopy (used in diagnostic investigations for colorectal and gastric cancers) (Han et al., 2024) and AI-aided processing of digital pathology and microscopy images (used in diagnostic investigations for cervical cancer) (Liu et al., 2025). Alhough it is within the scope of radiology, the current evidence on the use of AI-aided MRI interpretation for prostate cancer screening is very limited (Singh et al., 2026).

22 As well as the AI applications in radiological image processing outlined here, AI tools used to process non-imaging data are also being considered to support the work of radiologists. For example, another subfield of AI, called natural language processing, is being applied to process text-based data from radiology reports to generate recommendations for clinical follow-up (Kapoor et al., 2020). AI algorithms are also being used to develop cancer risk models to inform risk-stratified cancer screening approaches.

- Study reporting is often suboptimal, and programming code or training datasets are rarely made openly available (Anderson et al., 2022; Lee et al., 2025; Nagendran et al., 2020).
- Many algorithms are developed and validated using datasets from a single institution, limiting external validity and generalizability (Anderson et al., 2022; Brady et al., 2024; Uwimana et al., 2025) (see **Box 7** on page 21 for an overview of key validation terms).
- AI tools may be biased towards the populations whose data were used in their initial development, thus propagating inequitable care (Brady et al., 2024)

It is also important to take into account the influence of commercial interests in the development and implementation of AI tools. A multi-society statement from international radiological societies recommends that, to inform implementation, health care institutions should consider whether (1) commercial claims and (2) national health technology assessment approval/clearance data can be independently verified using local data sources (Brady et al., 2024). This statement also encourages continuous performance monitoring of AI tools using updated local datasets, to ensure the models remain valid for their target populations. Creating representative datasets suitable for these aims is resource-intensive, requiring dedicated staff for data curation, cleaning, organization, anonymization and annotation (Brady et al., 2024; Uwimana et al., 2025) (see **Box 10** for an example).

In summary, AI-aided cancer screening represents both an opportunity and a challenge. It could help alleviate radiology workforce constraints, streamline screening workflows and maintain quality in cancer screening, but its integration into practice will require careful attention to validation, transparency and real-world applicability.

4.2 How can AI-aided cancer screening be implemented within screening programmes to improve radiological workflow timeliness?

Radiology workforce readiness is essential for safe, trustworthy and effective adoption of AI in cancer screening

Radiology professionals are the intended primary end-users of the emerging AI/ML technologies for medical image interpretation. As such, it is important that professional radiology training evolve to help radiologists integrate these technologies into their clinical practice. In a recent survey of international radiology professionals (as part of INCISIVE[23] – an EU initiative aimed at informing the implementation of AI in cancer imaging), many respondents agreed that the use of technology may improve the cancer screening pathway by, for instance, automating tasks that tend to be repetitive and

Box 10. Resourcing a high-quality breast imaging dataset to support the development and testing of AI algorithms for screening mammography in Sweden

Investigators in Sweden developed a breast imaging dataset to serve as a high-quality platform for training and testing AI algorithms for screening mammography (Dembrower et al., 2020). The Cohort of Screen-Aged Women (CSAW) – a complete population-based cohort of women aged 40–74 years who were invited to undergo free mammography screening through the national breast cancer screening programme in the Stockholm region between 2008 and 2015 – served as the basis for the imaging dataset. The CSAW was derived by linking information held by the regional cancer centre (such as personal identification numbers of women eligible for screening and details of screening encounters) with the breast cancer quality register (containing information on diagnostic encounters, surgical variables and tumour features).

The CSAW was then linked to a radiological image repository, containing digital mammograms from the three breast centres that cover the Stockholm region: Karolinska University Hospital, Capio St. Göran's Hospital, and Southern General Hospital. Mammographic images of women who had been diagnosed with breast cancer were retrieved from their time of diagnosis and from their prior screenings. Based on 1 688 216 screening invitations between 2008 and 2015, a total of 1 182 733 examinations were captured, each containing four images (i.e. two views of each breast).

The well-established breast cancer screening programme in Sweden, high screening uptake and representative national cancer databases were key enablers of the breast imaging dataset development. Although curating such a dataset is a resource-intensive process, it has proved essential for testing and implementing AI-aided clinical workflows in Sweden. Some examples of basic AI performance parameters that can be evaluated using these data include the rates of abnormal interpretation, recall, cancer detection, false negatives and false positives, along with sensitivity, specificity and area under the curve. This dataset was also used to calibrate the performance of an AI tool that has been implemented for radiological image reading in routine clinical practice (see **Box 11** on page 28).

As the field of AI-aided radiological imaging interpretation grows, datasets such as the CSAW-derived breast imaging dataset can be used to address the following types of evaluative objectives:

- Increasing the sensitivity of AI-aided tumour detection algorithms;
- Establishing the external validity of emerging international AI cancer detection algorithms in a representative dataset;
- Developing risk prediction algorithms to support risk-stratified breast cancer screening;
- Supporting interactive education of clinicians through educational software by matching the proficiency level of a trainee with the difficulty level of patient cases.

Ultimately, there will be a need for international standards that define the appropriate methods for deriving robust datasets that are well-suited for AI algorithm validation and evaluation (Uwimana et al., 2025).

23 https://incisive-project.eu/ (accessed 16 July 2026).

time-consuming, including aspects of image interpretation (e.g. tumour contouring, image segmentation and image quality checking) (Hesso et al., 2023). By automating such time-consuming tasks and replacing the second human reader in image interpretation (as detailed in the previous section), AI tools may enable radiologists to devote more of their time to patient care. From a policy perspective, these perceived benefits highlight opportunities for health systems to alleviate health workforce shortages and improve screening capacity through targeted investment in AI-enabled tools.

Structured piloting and evaluation mechanisms are needed to ensure safe, evidence-based adoption of AI tools in clinical practice. Indeed, radiologist survey respondents highlighted the following priorities to facilitate health professional adoption of AI technologies (Hesso et al., 2023):

- High-quality trials that support AI tool validity, reliability, and effectiveness;
- Demonstration of the relative advantage of AI technology in comparison to current practice;
- Technology ease of use.

Additionally, radiologists emphasized the need to raise awareness and to provide training and education about AI technologies (Hesso et al., 2023). Notably, nearly three quarters of survey respondents did not have prior experience of adopting new technology to support their clinical practice, suggesting that the radiology workforce may not be prepared to adopt AI innovations (Hesso et al., 2023). This points to a system-level readiness gap that policy-makers must address through workforce development strategies. A lack of technical knowledge and understanding of AI tools may dissuade clinicians from trusting the outputs of AI systems or make them uncertain about how to incorporate these outputs into their decision-making processes (Hesso et al., 2023; Uwimana et al., 2025). Such barriers indicate the need for policies that embed AI literacy and competency requirements into training, accreditation and continuous professional development frameworks.

Evaluation of AI tools within health care institutions and provision of on-the-job training may facilitate the routinization of AI tools in clinical practice by adding to the evidence base, supporting continuous performance monitoring, and improving health professional awareness and knowledge (Brady et al., 2024; Hesso et al., 2023). For example, the Capio St. Göran's Hospital in Sweden was the first hospital in the world to adopt AI-aided mammography reading in their clinical workflows, following the completion of a clinical study that evaluated the accuracy of AI-aided strategies relative to usual care. This demonstrates how evidence generation combined with implementation support can build staff confidence and inform national policy on scaling AI in imaging services. The experience with the study, supplemented by additional training, led to high radiology staff buy-in by the time the tool was rolled out (see case study in **Box 11**).

Qualitative studies of both health care provider and patient views have raised concerns about the potential **unintended consequences** of implementing AI tools. In particularly high-volume, time-pressured environments, such as busy screening programmes, there may be a tendency to accept AI decisions without further evaluation or formulation of independent judgement (sometimes referred to as "automation bias") (Brady et al., 2024; Derevianko et al.,

Box 11. Developing an AI-aided screening mammography workflow for breast cancer screening in a Swedish hospital

In June 2023, the Capio St. Göran's Hospital in Stockholm, Sweden, became the first hospital in the world to implement an AI algorithm to act as a second reader for clinical review of screening mammography imaging. This came on the heels of a real-world study called ScreenTrust CAD (Dembrower et al., 2023), funded by the Swedish Research Council, Region Stockholm, the Swedish Cancer Society and the Korean software company Lunit Inc., which developed the AI algorithm (Insight MMG).

Before the AI-aided strategy, the standard of care workflow at the Capio St. Göran's Hospital involved two radiologists independently reading the mammogram and providing a judgement about whether the examination was normal (i.e. no suspicious signs were seen) or abnormal. If both readers assessed the image to be normal, the screening participant was notified of their negative result. If at least one reader judged the examination as abnormal, the case moved on to a consensus discussion, whereby two radiologists decided whether to recall the screening participant for further imaging. If the second examination showed another abnormal result, the person underwent a biopsy to receive a definitive diagnosis by a pathologist. The AI-aided strategy involved AI acting as one of the independent readers in the first stage of this workflow (i.e. before the consensus discussion), providing a numerical abnormality score. The abnormality threshold was calibrated using an enriched dataset of 6625 mammography examination images acquired between 2012 and 2015 at two Stockholm hospitals (Capio St. Göran's Hospital and Southern General Hospital), sourced from a large breast imaging database (see **Box 10** on page 27).

Four strategies were compared in the ScreenTrust CAD trial: (1) double reading by two radiologists (standard of care), (2) double reading by one radiologist and AI, (3) single-reading by AI, and (4) triple reading by two radiologists and AI. All AI-aided strategies performed comparably to the standard of care, with triple reading being the best performing strategy overall; double reading with AI showing slight superiority over the standard of care, with an increase of 4% in screen-detected cancers; and single-reading with AI being comparable but not superior to the standard of care. Overall, these findings suggest that double reading by one radiologist and AI may be a viable strategy in settings where the radiologist workforce is limited.

Prior to the trial, the investigators held a workshop with the hospital radiologists to explain the meaning of the AI scores and image markings. Throughout the trial, on-the-job training was provided to the hospital radiologists by the lead investigator. This training, along with the experience with the trial, allowed the staff to become well-acquainted with the AI tool by the time the AI-aided workflow was routinized in clinical practice (Hallesjö, 2023). A risk analysis preceded the introduction of the AI into clinical practice, which involved an assessment of the associated ethical and legal issues. The routinization of the AI-aided mammography reading strategy has allowed radiologists to devote more time to individual patient care.

2023; EDPS TechDispatch, 2023; Rubin, 2019; Uwimana et al., 2025). This may result in errors and unsafe patient care, as AI technologies have been shown to underperform with unusual or complex patient cases (Derevianko et al., 2023; Rubin, 2019; Uwimana et al., 2025). Relatedly, an overreliance on technology instead of professional expertise may, over time, lead to diminished clinical decision-making skills among radiology professionals (Brady et al., 2024; Derevianko et al., 2023; Hesso et al., 2023; Rubin, 2019; Uwimana et al., 2025), particularly among early career professionals who have been primarily trained to perform their tasks with the assistance of technology (Hesso et al., 2023; Rubin, 2019). The introduction of technological aids within and outside of medicine has been shown to reduce people's attention and perceptive skills, which may compromise patient safety (Rubin, 2019).

Overall, these issues suggest that the implementation of AI technology is better framed as a means to enhance radiology practice, rather than as a means to replace the role of health professionals (Hesso et al., 2023). As such, it is important that AI training and education strategies inform radiology professionals about the potential unintended consequences of implementing AI tools and how this may impact patient care (Brady et al., 2024; Derevianko et al., 2023). Co-creation, whereby radiology professionals collaborate with software developers on AI tools, may further ensure that these tools are fine-tuned, deployed and used in a safe and ethical[24] way (Brady et al., 2024; Geis et al., 2019).

Studies of patient and public perceptions of cancer screening processes show that patients want to fully understand their imaging results to have more productive conversations with their clinicians as part of informed decision-making (Derevianko et al., 2023). Although many patients understand and regard positively the potential role AI tools may play in streamlining their care and reducing waiting times on the path to cancer diagnosis (Hesso et al., 2022; Pesapane et al., 2024), discrepancies between clinician and AI judgments may undermine patient trust (Hesso et al., 2023; Madanay et al., 2025). A web-based randomized experiment of 1606 United States adults showed that when participants were prompted to imagine a scenario where their radiologist recommended less intensive follow-up than AI after LDCT lung cancer screening, participants were less likely to recommend or positively rate that radiologist (Madanay et al., 2025). Clinicians have expressed a need for information about **how to effectively and transparently interpret and communicate AI outputs to patients** (Derevianko et al., 2023; Hesso et al., 2023; Pesapane et al., 2024). One literature review suggested that AI involvement in cancer detection should be communicated to participants and patients as soon as possible in the screening pathway; however, there is limited evidence-based information about effective communication strategies in this context (Derevianko et al., 2023).

A key factor that may enable providers to adopt AI technology in their practice, mitigate unintended consequences and communicate clinical findings to patients is whether the technology relies on **explainable AI**. Explainable AI can be defined as the ability of AI tools "to provide clear and understandable explanations for their actions and decisions" (EDPS TechDispatch, 2023). The concept of explainable AI emerged in response to the "black box" aspect of some AI tools, where the logic or set of decisions according to which the AI system arrived at its output is opaque (Brady et al., 2024; EDPS TechDispatch, 2023). In qualitative interviews with radiology professionals, inability to understand how AI models work and what factors they considered in reaching their conclusions was cited among the main barriers to considering implementing these tools in clinical practice (Hesso et al., 2023). There is no consensus regarding the standard methodologies for developing explainable AI systems in the cancer screening context (Uwimana et al., 2025). Generally, it is expected that explainable AI models would offer radiologists detailed insights about which input data are relevant for the model, how to interpret the AI-derived output (e.g. as an indicator of probability of detecting cancer lesions on imaging), the certainty of the AI-derived results, and which variables are considered in AI decision-making (Brady et al., 2024; Uwimana et al., 2025).

24 A multi-society statement on Ethics of AI in Radiology identified the following key messages (Geis et al., 2019): (1) Ethical AI use in radiology should promote well-being, minimize harm, and ensure that the benefits and harms are distributed among the possible stakeholders in a just manner; (2) AI use in radiology should be appropriately transparent and highly dependable, curtailing bias in decision-making and ensuring that the responsibility and accountability remains with human designers and operators; (3) The radiology community should continue to develop AI codes of ethics and practice; (4) Radiologists remain ultimately responsible for patient care and will need to acquire new skills to continue to provide optimal patient care in the new AI ecosystem.

5. Cross-cutting considerations for implementing cancer screening innovations

As we advance towards the next generation of cancer screening approaches and technologies, there are critical cross-cutting considerations that will shape their successful integration into population-based screening programmes to ultimately achieve better cancer outcomes.

Public health education and communication is needed when cancer screening innovations are being deployed to ensure that they are acceptable to screening participants. In order to participate in cancer screening, people need to understand how to access and undergo the procedures, what the results mean, the follow-up options available to them, as well as the potential benefits (and relative harms) these procedures may carry. When cancer screening innovations introduce changes to the screening protocols, transparent communication of the reasons for these changes – and the underlying scientific evidence – can help maintain public trust in cancer screening interventions and support informed decision-making. Non-clinical and clinical community settings, including primary care and pharmacies, can be effective partners for educating and communicating with the public due to long-established rapport and trust. Furthermore, promoting digital and health literacy is crucial for any cancer screening innovations to be equitable and thus truly succeed at scale.

Health professional training on cancer screening innovations is essential to ensure that these innovations are effectively used in routine clinical practice. This means that, similar to patients and the public, health care providers need to understand the reasons for the changes to the screening protocols in order to trust them enough to implement them in their practice. Since innovations like self-administered tests, risk-tailored screening and AI-aided radiological image reading may be perceived as attempts to bypass clinical judgement, it is important to emphasize how these innovations can assist clinical practice, rather than hinder or replace it. Finally, health care providers play a crucial role in maintaining public trust and facilitating informed decision-making. In this light, they require support – such as knowledge translation tools – to communicate the results of innovative cancer screening procedures to screening participants and make technical information more accessible.

Human support and engagement remains critical for effective implementation of technology-based innovations within screening programmes' existing workflows. For instance, patient navigators, allied health professionals and community health workers can help distribute self-administered screening test kits, perform risk assessments, provide health education and reassurance, and coordinate linkage to follow-up care. As these professionals practice within community settings, their trusted relationships with community members may enable better uptake of self-sampling, risk assessments and adherence to subsequent services. This point is especially salient for vulnerable groups, who remain under-screened. In AI-aided radiological image reading, trained health care staff are essential for maintaining the accuracy of image interpretation and for communicating results to patients. Importantly, people are more likely to have confidence in innovative cancer screening approaches and technologies when they know that there is a human element underpinning their care.

Personalizing cancer screening approaches holds promise for increasing cancer screening uptake and for optimizing cost-effectiveness. For example, self-sampling test kits can be distributed within traditional clinical settings and community-based settings (including door-to-door, shopping, community and fitness centres, or religious institutions), as well as be mailed to the participants' homes. Similarly, as part of risk-stratified cancer screening, risk assessments can be carried out online, via mailed questionnaires or through mobile screening clinics set up in various community settings. After risk assessment, the resulting cancer screening protocols are tailored to people's risk profiles. These forms of personalization have the dual effect of (1) increasing access to screening by shifting care from the clinic to the community and meeting the screening participants where they are; and (2) directing cancer screening resources to those more likely to benefit, thereby reducing the potential harm of screening procedures and optimizing their benefit.

Robust data infrastructures are required to support the deployment of innovative cancer screening technologies. Once self-sampling test kits are distributed, comprehensive screening registers are needed to track screening participants' screening status, test results and any follow-up steps in the screening pathway. To identify the target population for screening under a risk-stratified approach, integrated datasets are needed to populate the risk calculators – for instance, linking screening registers with vaccination registers to determine HPV vaccination status and inform cervical cancer screening protocols; or linking screening registers with primary care electronic health records to determine smoking status and inform lung cancer screening protocols. In addition, the mathematical algorithms used in risk calculators or AI technologies need to be rigorously tested and validated using representative datasets to ensure that they are appropriate for the target population at hand, minimizing bias.

Compliance with ethical and governance frameworks, such as the EU GDPR, national and EU health technology approval processes, as well as emerging regulations like the European Health Data Space (EHDS) and the EU Artificial Intelligence Act, is essential for maintaining the principles of informed consent, privacy and confidentiality, and the prevailing clinical practice protocols. There is inherent tension between technological innovations requiring significant data inputs – such as cancer risk calculators or AI algorithms for image interpretation – and rules and regulations aimed at protecting personal health information. Developing national and international standards for data curation, linkage and sharing may reduce the barriers to innovation deployment, while ensuring that patient privacy remains protected to the highest possible degree.

Continued evaluations of implementation and feasibility are paramount to inform the implementation of cancer screening innovations. By virtue of being innovations, the real-world evidence on their feasibility, effectiveness, safety and cost-effectiveness remains underdeveloped. For instance, much of the current knowledge about risk-stratified screening and AI-aided radiological image reading stems from small diagnostic accuracy studies, often conducted within single institutions using retrospectively collected data, or modelling studies, which rely on hypothetical scenarios and assumptions. As such, prospective, real-world evaluations of innovations, using high-quality research designs, are much needed, alongside performance monitoring using screening programme data.

6. Conclusion: looking ahead

Self-administered cancer screening tests, risk-stratified screening and AI-aided processing of screening-related imaging are innovations that can truly transform the cancer screening pathway – including who is screened and how. These innovations have the potential to considerably improve screening access, quality and efficiency, as well as to help funnel cancer screening resources towards those most likely to benefit.

However, the real-world implementation of these innovations within population-based screening programmes requires a careful consideration of the programme setting. For instance, direct mailing of self-sampling test kits to under-screened groups may be more suitable within large programmes, while in-person distribution by trusted health care workers may be preferred in smaller communities and among the more vulnerable segments of the population. Either way, while self-sampling makes screening more accessible, additional interventions, such as patient navigation, are needed to ensure uptake and linkage to follow-up care.

Risk-stratified cancer screening introduces a new step – risk assessment (or risk calculation) – into the screening pathway. Key aspects of this step, such as who performs the risk assessment, at what time and where, depend on the risk calculator model chosen and the characteristics of the available health data infrastructure. Strong engagement with health professionals, including continuing education, training and co-creation, represents a key driver of successful implementation and routinization.

Given the rapid pace of development of AI tools, it is important that the AI models used are explainable – that is, that the path between their inputs and outputs is clear and traceable – in order for them to be adopted in routine clinical practice. AI tools must also be deployed ethically to support patient safety and ensure that they add value to care.

Overall, maintaining patient, public and health professional acceptability of cancer screening innovations through transparent communication and training, and resourcing rigorous testing and validation of new technologies using robust and representative population health datasets, are important for real-world implementation.

As these cancer screening innovations are implemented by countries to enact the 2022 screening recommendations of the Council of the EU, prospective evaluations using high-quality research designs will be needed to understand what works best in which context and for whom.

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