JACARDI

Joint action cardiovascular diseases and diabetes

# A Short Guide to Screening for Individuals at Increased Risk of Developing Cardiovascular Diseases and Type 2 Diabetes – Version 1.0

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[11] European Association for the Study of Diabetes (EASD)

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## Glossary of Acronyms

| Acronym | Description |
|---|---|
| AAMI | Association for the Advancement of Medical Instrumentation |
| ACCA | Acute Cardiovascular Care Association |
| ACNAP | Association of Cardiovascular Nursing and Allied Professions |
| ACC | American College of Cardiology |
| ADA | American Diabetes Association |
| AHA | American Heart Association |
| ANSI | American National Standards Institute |
| ASCVD | Atherosclerotic Cardiovascular Disease |
| BP | Blood Pressure |
| CANRISK | Canadian Diabetes Risk Assessment Questionnaire |
| CBG | Capillary Blood Glucose |
| CE | Conformité Européenne (European Conformity marking) |
| CVD | Cardiovascular Diseases |
| CGM | Continuous Glucose Monitoring |
| CLSI | Clinical and Laboratory Standards Institute |
| CUORE | Italian cardiovascular risk model |
| DBP | Diastolic Blood Pressure |
| DIAL2 | Diabetes Lifetime-perspective model |
| EHES | European Health Examination Survey |
| EHN | European Heart Network |
| EASD | European Association for the Study of Diabetes |
| EFPIA | European Federation of Pharmaceutical Industries and Associations |
| ESC | European Society of Cardiology |
| EU | European Union |
| EAPC | European Association of Preventive Cardiology |
| FINDRISC | Finnish Diabetes Risk Score |
| FPG | Fasting Plasma Glucose |
| GA | Grant Agreement |
| GDPR | General Data Protection Regulation |



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| | |
|---|---|
| GP | General Practitioner |
| HaDEA | European Health and Digital Executive Agency |
| HbA1c | Hemoglobin A1c (glycated hemoglobin) |
| HDL | High-Density Lipoprotein |
| IDF | International Diabetes Federation |
| IFCC | International Federation of Clinical Chemistry and Laboratory Medicine |
| IFG | Impaired Fasting Glucose |
| IGT | Impaired Glucose Tolerance |
| IMAGE | Initiative for Diabetes Action and Management (IMAGE Study Group) |
| INSP | Institutul Național de Sănătate Publică (Romania) |
| ISO | International Organization for Standardization |
| ISS | Istituto Superiore di Sanità (Italy) |
| ISH | International Society of Hypertension |
| JACARDI | Joint Action on Cardiovascular Diseases and Diabetes |
| JBS3 | Joint British Societies' cardiovascular risk prediction tool |
| LDL | Low-Density Lipoprotein |
| LIFE-CVD2 | Lifetime-perspective model for cardiovascular risk prediction |
| MAGGIC | Meta-Analysis Global Group in Chronic Heart Failure (risk calculator) |
| MDCG | Medical Device Coordination Group |
| MDR | Medical Device Regulation |
| MS | Member States |
| NCD | Non-Communicable Diseases |
| NHS | National Health Service (UK) |
| NYHA | New York Heart Association (heart failure classification) |
| OGTT | Oral Glucose Tolerance Test |
| PC | Personal Computer |
| POCT | Point-of-Care Testing |
| QRISK | Cardiovascular risk calculator developed in the UK |
| RBG | Random Blood Glucose |
| RECODe | Risk Equations for Complications Of type 2 Diabetes |
| RRS | Reynolds Risk Score |



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| | |
|---|---|
| SBP | Systolic Blood Pressure |
| SCORE | Systematic Coronary Risk Evaluation |
| SCORE2 | Systematic Coronary Risk Evaluation 2 |
| SMBG | Self-Monitoring of Blood Glucose |
| SMART | Secondary Manifestations of ARTerial disease (risk calculator) |
| STRIDE BP | Scientific organization for BP monitor validation |
| TC | Total Cholesterol |
| T2D | Type 2 Diabetes |
| TG | Triglycerides |
| THL | Finnish Institute for Health and Welfare |
| TIA | Transient Ischemic Attack |
| VPG | Venous Plasma Glucose |
| WHO | World Health Organization |

**Keywords**

Screening, Primary prevention, Risk assessment, Early detection, Population health, Stratification, Non-communicable diseases (NCDs), Cardiovascular diseases (CVD), Type 2 diabetes (T2D)



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## Abstract

The aim of this short guide, developed within the framework of the Joint Action on Cardiovascular Diseases and Diabetes (JACARDI), a European Joint Action co-funded by the EU4Health Programme, is to provide an overview of approaches for identifying individuals or segments of the population at increased risk of developing cardiovascular disease (CVD) or Type 2 diabetes (T2D). These approaches may include population-level monitoring, individual risk assessment, population segmentation, and also screening. When appropriately designed and implemented, such approaches can support primary prevention efforts by helping to target interventions that tackle harmful risk factors and encourage protective factors.

While not all risk assessment methods constitute formal screening programmes, they may still inform policies and practice. For instance, individual-level risk assessment can support clinical decision-making, whereas population-level stratification can guide broader public health strategies. In some cases, risk identification may also facilitate earlier diagnosis, provided that it is linked to follow-up, diagnosis and treatment pathways. However, any assumptions about improved health outcomes must be supported by evidence, and should consider the full pathway from identification to intervention.

This guide is intended as a quick reference, summarizing key concepts related to the use of risk assessment and stratification approaches in the context of CVD and T2D prevention, the focus being on primary prevention within a public health framework. For comprehensive discussions and detailed guidance on specific screening programmes, readers are encouraged to consult additional sources listed in this document.



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## Foreword

As the Director of Research, Development and Innovation at the Finnish Institute for Health and Welfare, I am pleased to present this document, which offers a concise guide for the screening of individuals at high risk for cardiovascular diseases (CVD) and Type 2 Diabetes (T2D) as one of the tools for reducing disease burden. These conditions continue to pose a significant burden on health systems across Europe, and early identification of those at increased risk is a critical step in preventing disease onset and improving long-term health outcomes.

This short guide provides practical recommendations for organizing and implementing screening activities and drawing on evidence-based approaches. We hope this guide serves as a useful tool for public health professionals, policymakers, and other stakeholders working to strengthen preventive strategies and promote health equity across Europe.

We thank all JACARDI project partners and experts who contributed to the development of this short guide.

Hanna Tolonen

Director of Research, Development and Innovation at the Finnish Institute for Health and Welfare



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The short guide was developed in the Joint Action on Cardiovascular Diseases and Diabetes (JACARDI), a European Joint Action co-funded by the EU4Health Programme.
JACARDI involves 21 European countries, which collaborate to reduce the burden of CVD and T2D and related risk factors at both individual and population level. The Joint Action addresses the full patient journey, from health promotion, screening to disease management, promoting an inclusive and sustainable approach that integrates social determinants of health, cultural diversity, and equity to strengthen health systems and reduce health inequalities. With this short guide, the aim is to facilitate decision-making for policymakers and other relevant stakeholders when exploring the options available for identifying individuals or segments of the population with increased risk to develop CVD or T2D. Keeping in mind that these screening activities should increase effectiveness, maximize benefits and minimize harms.

This guide was technically and conceptually led by the JACARDI team focusing on screening high-risk populations and individuals and produced under the guidance of Hanna Tolonen (Director of Research, Development and Innovation at the Finnish Institute for Health and Welfare (THL)). William Leysen (European Project Coordinator & Policy Advisor in CVD and Diabetes Prevention at Diabetes Liga - Belgium) was the editor of the guide and wrote substantial parts of it, with contributions from Alessandra Cardinale (ISS), Alexandra Cucu (INSP Romania), Aurélie Lampaert (Diabetes Liga), Beatrice Formenti (FPG), Benedetta Armocida (ISS), Benedetta Marcozzi (ISS), Carmen Angheluta (INSP Romania), Claudia Dima (INSP Romania), Claudia Giacomozzi (ISS), Eeva Rantala (THL), Fanny Monet (University of Antwerp), Giovanni Calcagnini (ISS), Hanna Elonheimo (THL), Jelka Zaletel (National Institute for Public Health Slovenia), Jorik Vergauwen (University of Antwerp), Laura Paalanen (THL), Luigi Palmieri (ISS), Massimiliano Petrelli (Regional Health Agency Marche Region), Mattei Eugenio (ISS), Petry Milos (INSP Romania), Roberta Papa (Regional Health Agency Marche Region) and Ruth Verdegem (Diabetes Liga).

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## Background

CVD and diabetes continue to pose significant global health challenges, representing major contributors to mortality, disability and morbidity across Europe.

- **Cardiovascular diseases** are a group of disorders of the heart and blood vessels. In JACARDI, we focus mostly on coronary heart disease and cerebrovascular disease. CVD remain the leading cause of death in Europe, accounting for 45% of all deaths, which translates to over 3.9 million deaths annually.[1]

- **Diabetes** is a chronic, metabolic disease characterized by elevated levels of blood glucose (or blood sugar), which leads over time to serious damage to the heart, blood vessels, eyes, kidneys and nerves. The most common type of diabetes is T2D, on which we will focus throughout this short guide. The burden of diabetes, particularly T2D, is also on the rise, with nearly 61 million individuals affected across Europe, a figure projected to increase to 67 million by 2030.[2] This rise can largely be attributed to the increase in prevalence of obesity, as well as the aging of the population.

These chronic diseases not only have profound health consequences but also impose enormous economic costs. In the EU, the estimated annual cost of CVD is around €300 billion[3], while the economic burden of T2D amounts to approximately €176 billion, much of which stems from treating preventable complications[4]. Together, these diseases account for a significant portion of healthcare expenditure and lost productivity, exacerbating socioeconomic inequalities and straining healthcare systems.

Most CVD and T2D cases are linked to **unmodifiable risk factors**, such as age, medical history, family history, as well as **modifiable risk factors**, such as smoking, unhealthy diets, sedentary lifestyles, obesity, and elevated blood pressure and cholesterol levels. When talking about European regions, it is important to clarify what each region entails. The European Union includes 27 countries,[5] WHO European Region includes 53 Member States,[6] IDF European Region includes 59 Member States[7] and ESC European Region includes 58 Member States.[8]

[1] European Society of Cardiology (ESC) (2024). Available online: https://www.escardio.org/The-ESC/Press-Office/Fact-sheets (Date last accessed: 07/02/2025)
[2] International Diabetes Federation (IDF) Europe (2023). Type 2 Diabetes: A preventable catastrophe? A call to action by IDF Europe. Available online: https://idf.org/europe/media/uploads/sites/2/2023/06/IDF-Europe_Type-2-Diabetes.-A-preventable-catastrophe.pdf (Date last accessed: 07/02/2025)
[3] Luengo-Fernandez, R., Walli-Attaei, M., Gray, A., Torbica, A., Maggioni, A. P., Huculeci, R., Bairami, F., Aboyans, V., Timmis, A. D., Vardas, P., & Leal, J. (2023). Economic burden of cardiovascular diseases in the European Union: a population-based cost study. European heart journal, 44(45), 4752–4767. https://doi.org/10.1093/eurheartj/ehad583
[4] Statista (2024). Health care expenditure due to diabetes worldwide in 2021, by region. Available online: https://www.statista.com/statistics/241831/health-care-costs-due-to-diabetes-worldwide-by-region/ (Date last accessed: 07/02/2025)
[5] European Union. EU countries [Internet]. Brussels: European Union; [cited 2025 Mar 12]. Available from: https://european-union.europa.eu/principles-countries-history/eu-countries_en
[6] World Health Organization. About WHO Europe [Internet]. Copenhagen: WHO Regional Office for Europe; [cited 2025 Mar 12]. Available from: https://www.who.int/europe/about-us/about-who-europe
[7] International Diabetes Federation. Europe [Internet]. Brussels: International Diabetes Federation; [cited 2025 Mar 12]. Available from: https://diabetesatlas.org/data/en/region/3/eur.html
[8] European Society of Cardiology. Member National Cardiac Societies [Internet]. Sophia Antipolis: European Society of Cardiology; [cited 2025 Mar 12]. Available from: https://www.escardio.org/The-ESC/Member-National-Cardiac-Societies


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The **WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases**[9] aims to reduce premature mortality from noncommunicable diseases (NCDs) by 25%, **halt the rise of diabetes and obesity,**[10] and **decrease hypertension prevalence** through cost-effective interventions[11] and global monitoring. These efforts align with the UN's Sustainable Development Goal 3, which targets a **one-third reduction in premature mortality from major NCDs** by 2030.[12] The WHO Regional Office for Europe supports these initiatives with a cross-programmatic approach, launching resources like a short guide and policy brief to enhance the effectiveness of screening programmes.[13] During the World Health Assembly in May 2022, WHO Member States have supported the creation of 5 new global targets for diabetes to be achieved by 2030, as part of recommendations to strengthen and monitor diabetes responses within national NCD programmes.[14] [15] The European Commission's "**Healthier Together**" initiative supports EU Member States in implementing effective policies to reduce the burden of major NCDs and improve overall health and well-being. Covering 2022–2027, it focuses on five key areas: health determinants, CVD, diabetes, chronic respiratory diseases, and mental and neurological health, emphasizing effective and early screening as a priority to enhance disease prevention and quality of life. **Screening programmes are highlighted as important public health tools to reduce the incidence of diseases, through early identification of individuals at increased risk of developing CVD or T2D, enabling access to treatment/care, thus reducing disease severity and improving population health outcomes**.[16]

Establishing effective screening programmes, however, requires a clear understanding of the terminology and methods, and should utilize standardized protocols that ensure consistency and equity across diverse populations—topics explored in the next chapters.

[9] https://www.who.int/teams/noncommunicable-diseases/governance/roadmap
[10] Global Action Plan for the Prevention and Control of Non-Communicable Diseases 2013–2020. Geneva: World Health Organization, 2013. Available online: https://iris.who.int/handle/10665/94384 (Date last accessed: 07/02/2025)
[11] Tackling NCDs: "best buys" and other recommended interventions for the prevention and control of noncommunicable diseases. Geneva: World Health Organization, 2017. Available online: https://iris.who.int/bitstream/handle/10665/259232/%20WHO-NMH-NVI-17.9-eng.pdf?sequence=1&isAllowed=y (Date last accessed: 07/02/2025)
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[15] World Health Organization. Seventy-fifth World Health Assembly: resolutions and decisions, annexes. Geneva: WHO; 2022. Available from: https://apps.who.int/iris/handle/10665/361637.
[16] European Commission, 2022. Healthier Together – EU Non-Communicable Diseases Initiative. Available at: https://health.ec.europa.eu/document/download/d843d53e-c1c1-4664-b31e-febf618d011a_en?filename=eu-ncd-initiative_publication_en_0.pdf.


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## Screening and its role in disease prevention

Disease prevention encompasses a range of strategies to reduce the burden of diseases by addressing their causes and risk factors before they can lead to significant health consequences. These strategies are typically categorized into three levels of prevention, each level playing a distinct role in safeguarding public health and ensuring timely interventions:

| | |
|---|---|
| **Primary Prevention** | Aims to prevent the onset of a disease by reducing risk factors and promoting overall health. This includes health promotion, risk factor reduction, evidence-based risk identification (e.g., FINDRISC or SCORE2), preventive interventions and policy actions. |
| **Secondary Prevention** | Focuses on the early detection of disease and timely intervention to halt disease progression and reduce complications. This includes evidence-based screening programmes for detection of undiagnosed disease, early diagnosis and treatment programmes before clinical manifestation of the disease appears,... |
| **Tertiary Prevention** | Focuses on managing existing diseases and preventing complications, co-morbidities, disability or further deterioration, minimizing long-term impact of chronic diseases. This includes monitoring and long-term disease management, supporting quality of life, preventing disability-related complications,... |

As previously mentioned, **screening** is highlighted as an important public health tool in disease prevention, either through early identification of individuals with increased risk of developing CVD or T2D (primary prevention), through early detection of CVD or T2D (secondary prevention), or through early detection of CVD and T2D related complications in patients (tertiary prevention).

To make screening an effective method for combating disease, it should not be viewed as a single or standalone test.[17] **Instead, screening is most effective when integrated into a comprehensive preventive healthcare strategy, ensuring that any detected issues are promptly addressed and managed adequately**.[18]

By viewing screening as a part of a structured pathway in preventive healthcare, rather than an isolated test, healthcare systems can ensure more effective prevention and management. For example, there is an inextricable link between risk identification and providing preventive healthcare (e.g. lifestyle guidance) to individuals at increased risk of developing T2D.[17] **Identifying individuals at increased risk of a health condition enables the implementation of preventive interventions or treatments, ultimately aiming to reduce the morbidity and mortality associated with the condition**.

[17] Raffle AE, Mackie A, Gray JM. Screening: evidence and practice. Second Edition ed. Oxford: Oxford University Press; 2019.
[18] WHO. Screening programmes: a short guide. Increase effectiveness, maximize benefits and minimize harm. Copenhagen: WHO Regional Office for Europe; 2020.



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**Screening-related terminology is frequently misused or conflated with related concepts**. The terminology and definitions used in JACARDI are summarized in the table below:

| | |
|---|---|
| **Screening** | A public health initiative involving the systematic or opportunistic application of tests, assessments, or procedures (screening instruments) within a defined population, with the aim of identifying individuals at increased risk of developing or having a certain disease or condition, before the onset of symptoms. |
| **Mass Screening** | Large-scale screening applied to a defined population group, typically based on minimal criteria, such as age, gender, or geography, and is also a form of population screening. |
| **Selective Screening** | Targeted at specific subgroups within the population deemed at increased risk based on criteria such as family history, medical history, behavioral factors, lifestyle factors, occupational or environmental exposures. Selective screening can be considered a form of population screening. |
| **Multiple (or Multiphasic) Screening** | Involves simultaneous screening for multiple conditions during a single session or encounter. |
| **Surveillance** | A long-term vigil over the health of individuals or of a population where screening examinations are repeated at intervals. In JACARDI, this definition is expanded to encompass the systematic and continuous collection, analysis, and interpretation of health-related data in a population, which can also be used for monitoring purposes regarding the evaluation of screening programmes. |
| **Population or Epidemiological Surveys** | Screening instruments used to elucidate the prevalence, incidence, and natural history of specific variables with JACARDI placing greater emphasis on the primary goal of such surveys being to generate epidemiological insights rather than to bring individuals to treatment. Population or epidemiological surveys are often used as an instrument for surveillance/monitoring. |
| **Early detection** | In JACARDI, adopted as an umbrella concept encompassing the timely identification of increased risk through screening, or confirmed disease through diagnosis. The former can be referred to as risk detection/risk identification, the latter as early disease detection/early diagnosis. |
| **Systematic Screening** | A structured form of screening conducted as part of a programme that proactively identifies and invites all individuals within a defined target population to participate in a screening programme. Selection is based on predetermined criteria such as age, gender, or specific risk factors, as outlined in screening policies, guidelines, or scientific evidence. |
| **Opportunistic Screening** | A form of screening that occurs during routine healthcare visits or encounters initiated for reasons unrelated to the specific disease or risk factor being screened for. Triggered either by a healthcare practitioners' offer or an individual's request and relies on the practitioner's clinical judgement to identify eligible candidates. Unlike systematic screening, it is based on the healthcare practitioners' access to individuals rather than the systematic identification/recruitment of participants. |

**It is important to keep in mind the multi-faceted nature of screening initiatives**. For instance, a newborn screening panel can simultaneously be classified as mass screening and multiple screening, while data collected from national or regional diabetes or CVD registries may also contribute to surveillance efforts. The way screening is carried out can affect its effectiveness and cost-effectiveness. Recognizing this, the 2020 WHO *Short Guide on Screening Programs* proposes a dimensional framework to describe the various ways screening can be conducted and their implications.



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## Deciding on the implementation of screening programmes

Deciding whether to start/continue/stop a screening programme requires careful consideration. The WHO Short Guide on Screening Programmes (2020)[19] provides a stepwise approach in making these decisions. This process is organized around two essential decision layers:

| | |
|---|---|
| **1. Determining justification for Screening** | This involves **assessing whether screening for a particular condition is warranted**, guided by the Wilson & Jungner (W&J) criteria. |
| **2. Assessing Appropriateness in Specific Contexts** | This step evaluates **whether screening**, that fulfills W&J criteria in general, **is suitable within a particular country or subnational setting**, taking into account local factors such as feasibility, cost, and political commitment. |

An adapted version of this decision-making framework, highlighting the key steps in the process, is presented in **Figure 1: 'Decision Framework to Start, Continue or Stop a Screening Programme (SP)'**.

Following this approach requires a substantial amount of evidence. **To help structure this evidence effectively, in JACARDI we have developed a template provided in Appendix 'Template for evaluating the design of a screening programme'**. This template is designed to be completed by the governance group or relevant structure and serves as the reference document for finalizing the decision-making process.

While this template offers a thorough framework, it can be **resource-intensive to complete**. At the national level, this may be feasible, but subnational stakeholders may lack the resources to conduct comprehensive evidence reviews. **To address this, it is recommended that such stakeholders:**

- **Leverage Existing Material:**
  - Build upon existing reviews, reports, or evidence syntheses from national or international sources to fill evidence gaps more efficiently.
- **Partner with other organizations:**
  - Collaborate with institutions or organizations that have the capacity to conduct more in-depth assessments, ensuring a thorough yet feasible approach to evidence gathering.

[19] World Health Organization. WHO screening principles and practice: ethical considerations in policy and implementation [Internet]. Copenhagen: WHO Regional Office for Europe; 2020 [cited 2025 Apr 4]. Available from: https://apps.who.int/iris/bitstream/handle/10665/330829/9789289054782-eng.pdf



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*Figure 1 - Decision Framework to Start, Continue or Stop a Screening Programme (SP)*



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## Determine whether the particular disease is suitable for screening

In 1968, Wilson & Jungner[20] published a set of principles to be used when making decisions to set up new screening programmes, based on their (cost-)effectiveness. When considering establishing a screening programme, a particular disease should comply with following principles:

| | |
|---|---|
| 1 | The disease sought should be an important health problem. |
| 2 | There should be an accepted treatment for patients with recognized disease. |
| 3 | Facilities for diagnosis and treatment should be available. |
| 4 | There should be a recognizable latent or early symptomatic stage. |
| 5 | There should be a suitable test or examination. |
| 6 | The test should be acceptable to the population. |
| 7 | The natural history of the disease, including development from latent to declared disease, should be adequately understood. |
| 8 | There should be an agreed policy on whom to treat as patients. |
| 9 | The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care. |
| 10 | Case-finding should be a continuing process and not a "once and for all" project. |

These criteria have been **reviewed and adapted several times** in the past two decades. There have been revisions for screening in the genetic age by **Andermann et al. in 2008,**[21] and more in comprehensive reviews from **Dobrow et al. in 2018.**[22] Similar criteria has been provided in the **European Health Examination Survey (EHES) Manual** in the framework of health examination surveys.[23] Assessing whether a disease meets the W&J criteria starts by **evaluating the disease burden** within the population. This can be achieved for example through analyzing register data, which provides information to determine prevalence, incidence, morbidity and mortality. Additionally, **understanding the underlying determinants**, including behavioral, environmental, genetic, and social factors, can further refine screening efforts. These determinants can often be identified through comprehensive health surveys. By systematically evaluating factors such as disease burden, natural history, availability of effective treatment, and acceptability of screening tests, we can design and implement screening programmes that effectively identify individuals at increased risk, facilitate early intervention, enhance cost-effectiveness, and ultimately reduce the overall burden of disease.

[20] Wilson JMG, Jungner G. Principles and practice of screening for disease. Geneva: World Health Organization; 1968. Public Health Papers 34. Available from: https://iris.who.int/handle/10665/37650
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## Establishing a group to lead the decision-making process, mapping of stakeholders and conducting a situational analysis

Establishing a **dedicated governance group/structure** is essential for leading decisions on starting, stopping, or continuing a screening program. Screening programmes, as part of a comprehensive preventive healthcare strategy, require a clearly defined "owner" of the governance that operates with functional connections to national regulatory bodies and key stakeholders, including the public, health professionals and policy makers.

This group must navigate the complex challenges inherent to balancing diverse interests and expectations concerning screening programmes. Once the governance group/structure is defined, the next essential step is **mapping relevant stakeholders** – the public, health professionals, policy makers – to engage them effectively in the decision-making process. Stakeholder engagement ensures that diverse perspectives are incorporated and helps build consensus around the screening program's objectives and outcomes.

**Examples: Screening for CVD and T2D**

In the context of screening for CVD and T2D, the governance group could include representatives from:

- **National and Regional Health Authorities:** Ensuring alignment with existing public health policies and strategies for chronic disease prevention.
- **Primary Care Providers' Associations:** Involving general practitioners, nurses, and other healthcare professionals who are often the first point of contact for patients at risk.
- **Specialist Care Providers' Associations:** Including endocrinologists, cardiologists, and other specialists who can offer expertise on screening thresholds, diagnostic criteria, and appropriate follow-up.
- **Patient Advocacy Groups:** Incorporating the perspectives of individuals living with or at risk of type 2 diabetes and cardiovascular diseases, which is essential for designing acceptable and accessible screening pathways.
- **Research Institutions and Academics:** Providing evidence-based insights to ensure that the screening programme is aligned with the latest scientific findings.
- **Non-Governmental Organizations (NGOs) and Professional Societies at Country or international level: National or Regional Patient organizations** (e.g. Diabetes Liga in Flanders, Belgium**)**, **European Society of Cardiology (ESC)**, or **European Association for the Study of Diabetes (EASD)**, which can offer valuable resources and promote collaboration across borders.



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## Conduct a situational analysis

**Owners and stakeholders should collaborate on a situational analysis to determine whether screening is (still) an appropriate strategy, and if so, which preventive function screening should serve (primary, secondary or tertiary prevention)**. This analysis takes into account the previously assessed principles of Wilson and Jungner, and makes an assessment of the local health system, the role screening might play and whether screening is the only and preferred course of action. WHO 2020 provides a checklist that can help with the situational analysis:

| | |
|---|---|
| 1 | Have primary preventive strategies been effectively implemented? |
| 2 | Does a comprehensive control plan exist for the condition of interest? |
| 3 | Have the core components of early diagnosis and high-quality treatment of symptomatic people been optimized? |

**Examples: Screening for CVD and T2D**

1. Have primary preventive strategies been effectively implemented?
   - Health promotion and education for general population such as awareness and public health campaigns.
   - Risk identification to support targeted preventive interventions (e.g., tailored lifestyle support), where appropriate.
   - Lifestyle interventions for high-risk populations such as healthy eating patterns, physical activity, smoking cessation, etc.
   - Environmental and policy-based interventions such as banning smoking in public places, etc.
   - Preventive drug therapies.

2. Does a comprehensive control plan exist for the condition of interest?
   - WHO Global Action Plan for the prevention and control of NCD's.
   - WHO NCD Best Buys and Quick Buys.
   - The European Commission's "Healthier Together" initiative
   - National or regional action plan on diabetes, national or regional action plan on CVD, national prevention plan, etc.

3. Have core components of early diagnosis and high-quality treatment of symptomatic people been optimized?
   - Structured healthcare landscape for CVD and T2D with national or regional early diagnosis protocols, treatment protocols, etc.
   - Accessible early diagnosis and treatment.

**Depending on the preventive function under consideration, affirmative answers to these questions can indicate that a screening approach may be warranted. If certain elements are still lacking in your specific country/region, it is advised to consider taking action to make improvements here prior to or alongside initiating screening activities and to integrate these elements in a comprehensive preventive healthcare strategy.**



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## In-depth evidence reviews on screening activities for T2D and CVD

The WHO Stepwise approach towards starting, continuing or stopping a screening programme recommends conducting an in-depth review of evidence on effectiveness and cost-effectiveness for possible screening approaches, using the GRADE framework, resulting in evidence-based recommendations or guidelines that policy-makers and researchers can adhere to. Over the past two decades, numerous recommendations and guidelines have been developed to address the role of screening in the prevention and management of T2D and CVD. These guidelines often reflect varying perspectives on the benefits, limitations, and cost-effectiveness of different screening approaches, with some advocating for systematic screening, while others emphasize a more opportunistic approach. International collectives such as the **IMAGE** Study Group, as well as organizations such as the **WHO**, the **ESC**, the **EHN**, and **IDF** have provided critical input, offering evidence-based recommendations tailored to different populations and healthcare contexts. **In this chapter, we aim to highlight the most significant recommendations, policy considerations and guidelines from the past two decades, providing an overview of their key insights and their implications for policy and practice.**



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**IMAGE CVD & T2D recommendations:**

The European Evidence-Based Guideline for the prevention of T2D states that **effective prevention of T2D and CVD requires a combination of whole-population approaches and targeted high-risk approaches**.[24] This recommendation is in line with the population and high-risk strategies as described by Geoffrey Rose's Strategy of Preventive Medicine.[25] The **whole-population approach** focuses on "national T2D and CVD prevention plans, advocacy, community support, fiscal and legislative measures, engagement of the private sector, media communication and increasing population knowledge and motivation". This strategy lays the groundwork for reducing disease burden by addressing modifiable risk factors on a larger scale. The **targeted high-risk approach** emphasizes the importance of identifying individuals with glycemic abnormalities at a primary care level, such as impaired glucose tolerance (IGT) or impaired fasting glucose (IFG), which significantly increase the risk of T2D and CVD, at a primary care level and, **in those with IGT, to screen for associated CVD risk factors (method not specified)**. Approximately 30% of people with IGT will convert to T2D within 5 years, making this group critical for intervention *(2010)*.

- **The IMAGE Study Group recommends a stepwise or multi-level screening approach** that can be conducted in **community-based setting**, starting with
    - **(1) an opportunistic screening identifying individuals at increased risk using a simple, non-invasive and inexpensive risk prediction tool** (initiated by health-care personnel or the population itself), followed by
    - **(2) Specific glycemic testing** (FPG, OGTT or HbA1c) of individuals at increased risk and lastly
    - **(3) Performing an OGTT on individuals with an elevated FPG or HbA1c**. In CVD patients, an OGTT should be administered to all patients[24]. *(2010)*
- In **routine clinical practice, the IMAGE Study Group recommends a systematically targeted screening approach**, starting with **a pro-active identification** of all people with various combinations of risk factors (according to IMAGE criteria) **through data from GP medical files or health insurance companies, etc.** Alternatively, **the risk prediction tools** mentioned above can also be used to gather necessary data.[24]

[24] Paulweber, B., Valensi, P., Lindström, J., Lalic, N. M., Greaves, C. J., McKee, M., Kissimova-Skarbek, K., Liatis, S., Cosson, E., Szendroedi, J., Sheppard, K. E., Charlesworth, K., Felton, A.-M., Hall, M., Rissanen, A., Tuomilehto, J., Schwarz, P. E., & Roden, M., for the Writing Group on behalf of the IMAGE Study Group. (2010). A European evidence-based guideline for the prevention of type 2 diabetes. Hormone and Metabolic Research, 42(Suppl. 1), S3–S36. https://doi.org/10.1055/s-0029-1240928

[25] Rose, G., Khaw, K. T., & Marmot, M. (2008). Rose's strategy of preventive medicine (Updated ed.). Oxford University Press. https://doi.org/10.1093/acprof:oso/9780192630971.001.0001



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**WHO HEN policy considerations on CVD screening:**

- **WHO advises against initiating population-level screening programmes for either CVD risk or its risk factors in the European region**, referring to recent evidence that questions their effectiveness and suggests a risk of adverse effects such as overtreatment and overdiagnosis.[26] *(2024)*
- **WHO urges MSs to review existing population-level screening programmes for CVD risk and CVD risk factors and to consider alternative methods to reduce the CVD burden.**[26] *(2021)*
- **WHO suggests cardiovascular disease risk assessment in patients who may be at higher risk by presence of a CVD risk factor (aged over 40 years, history of tobacco use, overweight, known hypertension/diabetes, history of premature CVD, diabetes or kidney disease in first degree**). **WHO provides following protocols for assessment and management of CVD risk, with hypertension, diabetes, and tobacco use as entry points:**
    - The standardized risk prediction tools developed by WHO (e.g. the regional WHO CVD risk charts).[27,28]
    - The Package of Essential Non-communicable disease interventions (WHO PEN). (2020)
    - The HEARTS technical package on risk-based CVD management in this context. *(2020)*
- WHO suggests cardiovascular disease risk assessment at or after the initiation of pharmacological treatment for hypertension, but only where this is feasible and does not delay treatment.[29] (2021)

**WHO HEN policy considerations on T2D screening:**

- **WHO advises against initiating population-level screening programmes** for either T2D or intermediate hyperglycaemia.[30] *(2024)*
- **WHO suggests MSs to review the rationale for existing systematic population-level screening programmes for T2D** or intermediate hyperglycaemia and consider stopping them in favour of exploring alternative approaches to reducing the burden of T2D and its complications.[30] *(2024)*
- **WHO advises that if new or expanded population screening programmes are initiated**, to do so in a manner that **incorporates research** so that the impact on health outcomes and costs on health systems can be measured.[30] *(2024)*
- WHO acknowledges that **caution is warranted in drawing firm conclusions on the potential benefits and harms of population-level screening for T2D** because the evidence base is small, study populations are not generalizable to screening populations and, in general, studies were not adequately powered to detect differences in longer-term health outcomes between groups.[30] *(2024)*

[26] Jørgensen T, Rotar O, Bogh Juhl C, Linneberg A. What is the effectiveness of systematic population-level screening programmes for reducing the burden of cardiovascular diseases? Second edition. World Health Organization. Regional Office for Europe; 2024. Available from: (https://iris.who.int/handle/10665/375993).

[27] WHO. (2020a). HEARTS: technical package for cardiovascular disease management in primary health care: risk-based CVD management (9240001360).

[28] WHO. (2020c). WHO package of essential noncommunicable (PEN) disease interventions for primary health care (9240009221). W. H. Organization.

[29] World Health Organization. Guideline for the pharmacological treatment of hypertension in adults. Geneva: World Health Organization; 2021. Available from: https://iris.who.int/handle/10665/344424. License: CC BY-NC-SA 3.0 IGO.

[30] Stinton, C., Mansbridge, A., Williams, H., Herath, D., Parr, J., Grove, A., Kudrna, L., Rotar, O., Johnson, S. A., Oyebode, O., Al-Khudairy, L., & Taylor-Phillips, S. (2024). What is the effect of population-level screening of asymptomatic adults for type 2 diabetes mellitus or intermediate hyperglycaemia on health outcomes? WHO Health Evidence Network (HEN) synthesis report 79. Copenhagen: WHO Regional Office for Europe. https://apps.who.int/iris/handle/10665/37650



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- **WHO suggests that an opportunistic screening approach for individuals who may be at higher risk of developing** T2D may be justified provided it is based on clear, evidence-based policies.[31] *(2003)*

**European Society of Cardiology recommendations on CVD screening:**

- **ESC recommends systematic global CVD risk assessment in individuals with any major vascular risk factor** (i.e. family history of premature CVD, FH, CVD risk factors such as smoking, arterial hypertension, diabetes, raised lipid level, obesity, or comorbidities increasing CVD risk). *(2021)*
- **ESC supports the consideration of systematic or opportunistic cardiovascular risk assessment in the general population** in men >40 years of age and in women >50 years of age or postmenopausal with no known ASCVD risk factors.[32] *(2021)*

**European Society of Cardiology recommendations on T2D screening:**

- **ESC recommends** that in the general population and people with assumed abnormalities, the appropriate screening strategy is a **stepwise or multi-level screening approach**
  - **(1) starting with a T2D risk score;**
    followed by
  - **(2) investigation of individuals with a high value with an OGTT or a combination of HbA1c and FPG**.[33] *(2013)*
- **ESC recommends using interventions for prevention of T2D in a hierarchical approach**, starting with:
  - (1) individuals at the highest risk (IGT, IFG, or metabolic syndrome);
    followed by
  - (2) those with intermediate risk factors like obesity or hypertension
    and then
  - (3) the general population.
  - Adjusting the intensity of the intervention according to the risk level, is recommended, given the fact that resources are limited. This approach should also integrate education and support to ensure patients understand their risks and the benefits of preventive actions. Special care is needed to communicate with low-educated individuals.[24]
- **ESC recommends that in CVD patients, no diabetes risk score is needed but T2D screening using FPG and/or HbA1c** measurement is indicated, as this group is at an increased risk of T2D and shows worse clinical outcomes compared to individuals with normal glucose metabolism.[34] **An OGTT measurement is indicated if HbA1c and/or FPG are inconclusive**, since people belonging to these groups may often have diabetes revealed only by an elevated 2hPG (postprandial hyperglycemia).[35] The oral glucose tolerance test (OGTT) can thus detect cases of hyperglycemia, which might be missed by FPG and HbA1c. *(2013)*

[31] World Health Organization. (2003). Screening for type 2 diabetes: Report of a World Health Organization and International Diabetes Federation meeting. Department of Noncommunicable Disease Management. WHO/NMH/MNC/03.1. Geneva: World Health Organization.
[32] Visseren, F. L., Mach, F., Smulders, Y. M., Carballo, D., Koskinas, K. C., Bäck, M.,...Capodanno, D. (2021). 2021 ESC Guidelines on cardiovascular disease prevention in clinical practice. European heart journal, 42(34), 3227-3337
[33] European Society of Cardiology's 2013 Guidelines on diabetes, pre-diabetes, and cardiovascular diseases
[34] Marx, N., Federici, M., Schütt, K., Müller-Wieland, D., Ajjan, R. A., Antunes, M. J.,...Eliasson, B. (2023). 2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes. European heart journal, 44(39), 4043-4140
[35] European Society of Cardiology's 2013 Guidelines on diabetes, pre-diabetes, and cardiovascular diseases


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**European Heart Network recommendations on CVD screening:**

- **Systematic population level screening programmes**, in the form of adult health checks, could be effective in reducing risk factors for CVD in the short term, but are proven **not** to be **effective in the long term in reducing total CVD mortality in Northwestern European countries**. Yet **sufficient evidence is lacking from countries with high prevalence of important risk factors, as well as CVD morbidity and mortality, notably Eastern European countries**, and therefore **more research is needed** in those contexts. (2020)
- **Identifying individuals at high risk of cardiovascular disease should be a standard part of medical consultations in general practice** and supported by health care systems. (2020)
- The potential of **stratifying the population into risk groups using available data from electronic health records** should be further explored. (2020)
- Screening for abdominal aortic aneurysm is effective, yet future programmes must continue to target high risk individuals (e.g., family members of persons with AAA, and patients with CVD) and must consider the reduction of smoking rates and improved prevention and treatment options.
- **More research is needed to identify optimal strategies for screening specific cardiovascular conditions, such as atrial fibrillation**. (2020)
- **Cascade screening** should take place for family members of those with proven familial hypercholesterolaemia and where very high levels of blood cholesterol are found in individuals.
- **Evidence-based, targeted outreach and screening in selected settings and to specific population groups known to be at high risk are more likely to be effective than population level screening programmes**. This includes screening of family members in certain cases (cascade screening). (2020)
- In all cases, **programmes for screening cardiovascular risk should be well organised and conducted as a series of sequential steps** (**including lifestyle interventions**) that form a pathway and be sufficiently supported with financial, human, and technological resources. (2020)
- The European Heart Network (EHN) recommends that the EU establish a joint action/network of Member States, supported by experts, to identify the most effective policies, measures, and programmes for reaching out to and managing individuals at high risk of developing cardiovascular disease and detect those with specific, highly treatable cardiovascular conditions.[36] (2020)

[36] European Heart Network. Early detection of cardiovascular disease – an update from the European Heart Network. Brussels: European Heart Network; 2020. Available from: http://www.ehnheart.org/



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**International Diabetes Federation recommendations on T2D & CVD screening:**

- **IDF emphasizes that diabetes risk scores should be accompanied by a comprehensive and user-tailored explanation** to raise risk awareness and improve the understanding of T2D and its risk factors, while minimizing negative effects (e.g. emotional distress)[37]. *(2006)*
- **IDF recommends a general population approach**, prioritizing the **creation of societal conditions conductive to healthy lifestyles**, while giving a **lower priority to population-based screening** for diabetes, when resources are limited.[38] *(2010)*
- **IDF recommends opportunistic screening to identify high-risk individuals**, with a strong focus on individuals at increased risk (i.e. age +45, obesity, increased waist circumference, hypertension and family history of diabetes) **visiting local health-care facilities** (e.g. general practitioners, nurses, and pharmacists)[39,40]. In this context, the **IDF recommends the use of** a locally validated screening test, such as the Finnish Diabetes Risk Score (**FINDRISC**)[41] **risk prediction tool (self-administered/administered by healthcare providers). If a locally validated screening test is unavailable, measurement of fasting blood glucose should be used as a screening test**. *(2017)*
- **IDF emphasizes the importance of following up on:**
    - Positive screening results with both diagnostic procedures and diabetes prevention programmes (e.g. advice on healthy lifestyle changes).
    - Negative screening results by repeating the screening instrument at least every three years.[40] *(2017)*
- **IDF acknowledges that rigorous clinical research** studying the effectiveness of population-level screening for pre-diabetes or diabetes **is currently lacking**[42], although it is known that T2D remains underdiagnosed and its risk factors are widely spread in the European population.[43] *(2021-2023)*

[37] Adriaanse, M. C., & Snoek, F. J. (2006). The psychological impact of screening for type 2 diabetes. Diabetes/metabolism research and reviews, 22(1), 20-25.

[38] Paulweber, B., Valensi, P., Lindström, J., Lalic, N. M., Greaves, C. J., McKee, M.,...Szendroedi, J. (2010). A European evidence-based guideline for the prevention of type 2 diabetes. Hormone and Metabolic research, 42(S 01), S3-S36.

[39] Alberti, K. G., Zimmet, P., & Shaw, J. (2007). International Diabetes Federation: a consensus on Type 2 diabetes prevention. Diabet Med, 24(5), 451-463. https://doi.org/10.1111/j.1464-5491.2007.02157.x

[40] International Diabetes Federation. (2017). IDF Clinical Practice Recommendations for managing Type 2 Diabetes in Primary Care

[41] Lindström J, Tuomilehto J. The diabetes risk score: a practical tool to predict type 2 diabetes risk. Diabetes Care. 2003 Mar;26(3):725-31. doi: 10.2337/diacare.26.3.725. PMID: 12610029.

[42] American Diabetes Association. (2023). 2. Classification and diagnosis of diabetes: standards of care in Diabetes. Diabetes Care, 46, S19-S40.

[43] International Diabetes Federation. (2021). Diabetes Atlas Factsheet: Diabetes in Europe in 2021.



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JACARDI suggestions on T2D and CVD Screening:

Based on the evidence and recommendations presented, JACARDI proposes following suggestions for revised recommendations on opportunistic (individual-level) and systematic (population-based) screening for T2D and CVDs:

**Surveillance**

Regular national or regional health surveys should be conducted to assess the current health status, risk factor prevalence, and trends at the population and sub-group levels of a certain region. This data is essential for informing policy actions, monitoring the impact of screening initiatives for T2D and CVD, and guiding targeted prevention programs.

**Opportunistic Screening**

Opportunistic screening for T2D should be conducted using a stepwise approach:

1. **Identify individuals at increased risk of developing T2D** using T2D risk prediction tools (e.g. FINDRISC)*, or alternatively using data from GP medical files, focusing on risk factors such as age >45, obesity, hypertension, family history of DM;
2. **Follow-up** individuals meeting or exceeding the high-risk threshold* **with glycemic screening instruments** (e.g., FPG, HbA1c, OGTT)** to categorize glycemic status;
3. **Follow-up** high risk individuals **according to their glycemic categorization**:
   - **Normal:** Link individuals to preventive lifestyle guidance on modifiable lifestyle factors if present and repeat risk assessment with risk prediction tool (e.g. FINDRISC) every three years.
   - **Intermediate Hyperglycaemia:** Link individuals to preventive lifestyle guidance programs on modifiable lifestyle factors if present and recommend further screening for CVD risk factors using CVD risk prediction tools and/or targeted clinical protocols. These individuals should repeat risk assessment with risk prediction tool (e.g. FINDRISC) on a yearly basis
   - **DM:** Ensure diagnostic follow-up with a confirmatory FPG, HbA1c, or OGTT*

Opportunistic screening for CVD may be considered:

- **In individuals who may be at higher risk by presenting one or more of following CVD risk factors:** age > 40 years, history of tobacco use, overweight, known hypertension/DM, history of premature CVD, DM or kidney disease in first degree relatives.
- **If individuals presenting with these risk factors are followed-up**, using CVD screening instruments such as CVD risk prediction tools and/or targeted clinical protocols (e.g. protocols described in WHO PEN and WHO HEARTS).

**Systematic Screening**

Systematic screening for CVD and in a lesser degree T2D are not advisable based on current evidence reviews (WHO HEN).

This should however not hinder:

- **The initiation of research efforts** evaluating the long-term outcomes and cost-effectiveness of T2D and CVD screening (see below);
- **The continuation of existing screening programs** that embed research components and assess their cost-effectiveness and health outcomes.

Above remarks are especially important for the Systematic Screening of T2D, about which the current WHO HEN evidence warrants caution in drawing firm conclusions on the potential benefits and harms of screening for T2D because the evidence base is small, study populations are not adequately powered to detect differences in longer-term health outcomes between groups.

**Research**

Research efforts (preferably RCTs and longitudinal studies) evaluating the long-term outcomes and cost-effectiveness of population-level and individual-level T2D and CVD screening can help to improve the quality of evidence reviews by:

- Conducting them in areas where evidence gaps exist or where new scientific developments necessitate a re-evaluation of prior recommendations.
- Aligning existing T2D and CVD screening programs across Member States to generate greater volumes of standardized evidence on cost-effectiveness and health outcomes.

* Screening instruments, diagnostic criteria and cut-off values are usually regionally defined, based on local regulation and available resources. Where possible, efforts should be made to harmonize these values, criteria and instruments internationally.

** Different glycemic screening instruments are discussed are discussed in the subchapter "Glycemia-related measurements"



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## Evaluate the design of existing or potential new screening programmes in your region:

**Following the identification of suitable screening approaches, an in-depth evaluation of their screening designs for local implementation/continuation should be conducted.**

**Ethical framework for the screening program:**

The **Wilson & Jungner criteria** already offer a foundational set of principles to evaluate whether a screening programme is likely to be effective and cost-effective. While these criteria address some ethical aspects of screening—such as the unethical use of limited resources on ineffective programmes—they do not provide a comprehensive ethical framework.

Effective decision-making about screening programmes requires considering a broader range of ethical principles. The WHO short guide on screening programmes presented a pragmatic set of values for consideration:

- Respect for dignity and autonomy
- Non-maleficence and beneficence
- Justice and equity
- Prudence and precaution
- Honesty and transparency

Additionally, it should be stated that for a screening programme to be ethically justified, the **potential benefits must clearly outweigh the possible harms**.[44] In case of CVD and T2D, following potential benefits and possible harms can be considered:

| | |
|---|---|
| Benefits | Increasing awareness on own health condition |
| | Reducing severity, including reduced need for treatment |
| | Reducing incidence |
| | Reducing deaths |
| Harms | Overdiagnosis/overtreatment |
| | False negatives |
| | False positives |
| | Diverting health resources |

Moreover, policymakers often use different ethical frameworks, so **not only benefits vs. harms** is used, but also the **cost-effectiveness and resource allocation** of the screening program. **Taking these ethical frameworks into consideration during the decision-making process can promote a more thorough assessment, guiding policymakers to make informed, equitable, and responsible decisions.**

[44] World Health Organization Regional Office for Europe. Screening programmes: a short guide. Increase effectiveness, maximize benefits and minimize harm. Copenhagen: WHO Regional Office for Europe; 2020. Licence: CC BY-NC-SA 3.0 IGO.



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**Depending on screening approach, following International ethical guidelines should also be considered:**

- **The Declaration of Helsinki**, "Ethical Principles for Medical Research Involving Human Subjects",[45] is considered the cornerstone of ethical standards in health research, emphasizing protecting participants' life, health, dignity, integrity, self-determination, privacy, and confidentiality. It also addresses ethical review, study personnel qualifications, voluntary informed consent, and the inclusion of vulnerable populations.
- **The Belmont Report**, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research"[46] outlines the difference between "practice" and "research" in the field of biomedicine. The purpose of medical practice is to provide diagnosis, preventive treatment, or therapy while research develops or contributes to generalizable knowledge and usually has a protocol to follow.
- **The Recommendation of the Committee of Ministers No. R(90) 3** concerning medical research on human beings[47] lists similar topics to the Declaration of Helsinki.
- **The Oviedo Convention on Human Rights and Biomedicine**[48] focuses on bioethical questions such as genetic testing.
- **Council of Europe's 2005 Additional Protocol to the convention on Human Rights and Biomedicine, concerning Biomedical Research**[49], emphasizes informed consent, human welfare, and protection of vulnerable individuals. It mandates ethical review, risk minimization, data confidentiality, and includes guidelines for specific scenarios, such as pregnancy or emergencies, along with provisions for compensation and sanctions for rights violations.
- **Council of International Organizations of Medical Sciences and WHO in 2002: International Ethical Guidelines for Biomedical Research Involving Human Subjects**[50] provides guidelines for applying ethical standards and establishing ethical review mechanisms for biomedical research.
- **Local procedures for obtaining ethical approval** from local/regional/national Ethics Committee
- **Procedures for the preparation of the informed consent.** EHES Manual, Part A[51] has guidelines for preparation of the informed consent and how informed consent should be obtained from participants.

[45] World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects. 2008. Available from: https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2008.pdf
[46] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: ethical principles and guidelines for the protection of human subjects of research. Washington, DC: U.S. Department of Health and Human Services; 1979. Available from: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html
[47] Council of Europe, Committee of Ministers. Recommendation No. R (90) 3 concerning medical research on human beings. Strasbourg: Council of Europe; 1990. Reprinted in: International Digest of Health Legislation 41. Available from: http://hrlibrary.umn.edu/instree/coerecr90-3.html
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[50] Council for International Organizations of Medical Sciences. International ethical guidelines for biomedical research involving human subjects. Geneva: CIOMS; 2016. Available from: https://cioms.ch/wp-content/uploads/2016/08/International_Ethical_Guidelines_for_Biomedical_Research_Involving_Human_Subjects.pdf
[51] Tolonen H, editor. EHES manual: part A. Planning and preparation of the survey. Helsinki: National Institute for Health and Welfare; 2016. Available from: https://www.julkari.fi/handle/10024/131502


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**Legal or regulatory framework for the screening programmes**:

Legislation and regulatory frameworks should generally support the governance process related to screening programmes. Generally speaking, the regulatory framework for a screening programme varies by country, covering legal, ethical and scientific aspects to ensure safety, effectiveness and protection of participants' rights. Regarding general health regulations, a screening programme is a part of the public health protection system and must comply with national and international regulations. In the EU, preventive screening is regulated by the national health directives of individual Member States, but also by shared guidelines such as the recommendations of the European Council on specific diseases. This section highlights specific national and international regulations that can influence the implementation of screening programmes throughout EU Member States.

*Regional or national regulations of individual member states:*

JACARDI, in collaboration with JANFP4Health and National Focal Points for the Health Programme, conducted a survey in 32 European countries. The goal was to assess the current state of CVD and diabetes prevention and management by examining legal and strategic frameworks, intersectoral approaches, equity-oriented policies, funding mechanisms, and service delivery capacity.

A section of the survey was dedicated to the screening high-risk populations. The data collection period was from 2 April 2024 to 7 June 2024. Responses are available from 18 out of 21 countries, participating in JACARDI (Belgium, Croatia, Czech Republic, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Malta, Norway, Poland, Portugal, Romania, Slovenia, Spain and Ukraine). Slovakia, which is not a JACARDI partner country, provided responses for diabetes.

In summary, the survey findings indicate significant variability in legislative and strategic frameworks for screening individuals at high risk of developing CVD and diabetes across European countries. In 8/18 countries, no specific legislation is in place for high-risk screening, while in others, the legislation may or may not be disease-specific. However, an explicit institutional commitment to promoting screening activities is present in 13/18 countries, highlighting a recognition of its importance. National strategic frameworks for screening exist in 9/18 countries, with frameworks under development in 4/18 countries. **Given this diversity, a common EU initiative focused on legislative harmonization and strategic coordination could strengthen preventive efforts, enhance early detection, and improve population health outcomes across Europe.**



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*International regulations applicable for all member states*

**Screening programmes must comply with international legal frameworks** to guarantee scientific validity, ethical integrity, and data protection. While each EU member state regulates screening within its own healthcare system, **certain EU-wide and global regulations apply uniformly**, **ensuring consistent safety, quality, and transparency**. These include requirements for **scientific validity, participant protection, ethical approval, data privacy (General Data Protection Regulation, GDPR), and medical device regulation (MDR)**.

The following key international regulations influence the implementation of screening programmes across EU Member States:

- **CE Mark (Conformité Européenne):** The CE mark indicates that a product complies with EU safety, health, and environmental protection standards. Screening instruments used in programmes must demonstrate scientific validity, adhere to high-quality standards, and use CE-marked medical devices (screening instruments) where applicable. Approval processes, including Health Impact Assessments and ethics committee reviews, are required before implementation.
- **EU Regulation 2017/745 (MDR):** MDR sets stricter requirements for medical devices, ensuring their safety, effectiveness, and quality before they can obtain a CE mark. A medical device is: *"Any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: Diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease."* Screening programmes utilizing risk calculators must determine whether these tools qualify as software medical devices under MDR, particularly if they influence clinical decision-making.
- **Regulation (EU) 2016/679 (GDPR):** GDPR regulates the collection, processing, and storage of personal data, including health data, ensuring privacy and security. Given that screening programmes and their screening instruments involve collecting and processing health data, they must comply with the GDPR. This includes obtaining explicit and written informed consent, implementing enhanced security measures to prevent data breaches, and ensuring transparency about data collection and processing.
- **Council Recommendations**: In addition to legally binding EU regulations, Council Recommendations play a crucial role in guiding the implementation of screening programmes across EU Member States. While they are not legally binding, they represent a political commitment by Member States to align their national health policies with evidence-based EU priorities**. A key example is the Council Recommendation on Strengthening Prevention through Early Detection: A New EU Approach on Cancer Screening (2022)**, which updates and replaces the 2003 Council Recommendation on cancer screening (2003/878/EC). **No equivalent EU-wide Council Recommendation exists for CVD or T2D screening.**



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*Example: how international legislation can influence screening activities in member states:*

Risk prediction tools (p. 30) can play an important role in the prevention of CVD and T2D. The risk prediction tool can predict an individual's likelihood of developing a disease based on several factors (e.g., age, lifestyle, biomarkers, etc.) and can thus be considered a form of prognostic tool. **Under MDR, a prognostic tool qualifies as a medical device if used for predicting disease progression or adverse events, as well as guiding clinical decisions** (e.g., identifying individuals with increased risk of developing T2D or CVD needing preventive measures or closer monitoring).

There is a substantial difference between paper-based and software-based risk calculations. The risk score itself is not the issue—this parameter is generally reliable—but responsibility for errors differs. In paper-based calculations, the healthcare professional is responsible, whereas in software-based ones, responsibility lies with the manufacturer. Since December 2022, the Medical Device Coordination Group (MDCG) Borderline and Classification Manual explicitly classifies "medical calculators" as medical devices under MDCG 2019-11, subjecting them to at least Class IIa risk classification. **To comply with MDR, risk calculators must ensure clinical validation, bias mitigation and transparency**.

A key objection concerns risk score calculators that digitalize paper-based or published clinical rules already used in practice. The EFPIA (European Federation of Pharmaceutical Industries and Associations) raised this in its September 2024 position paper, criticizing the Borderline and Classification Manual's interpretation and proposing changes. EFPIA suggests excluding certain simple medical calculators from MDR classification if they meet one of these criteria:

1. *Calculations that contain few variables, use basic functions available on a calculator and can be easily verified by the intended user; or*
2. *Digitalize paper-based or other published clinical rule routinely used in clinical practice and research, and it does not make treatment or diagnosis decisions that lead to an immediate or near-term actions; or*
3. *Digitalize dosage calculation that automates the arithmetic operation for medicinal product dosage calculation according to the medicinal product indications to facilitate prescription and/or dispensation by health care professional.*"

This position has not yet been formally accepted by the European regulatory framework, so it remains that a risk score calculator must be considered a medical device. However, this must not block or stop screening programmes, which can still be carried out while being aware of the current regulatory framework. JACARDI recommends implementation or usage of risk calculators with following considerations:

- Ensure medical personnel understand the responsibility of using non-CE-marked risk calculators.
- Inform patients (informed consent) about the screening method based on a non-CE-marked risk calculator.
- Use risk calculators implemented on CE-certified platforms such as the U-prevent website (https://u-prevent.com/calculators).
- Add clear disclosure and inform all users (patients, clinicians, operators, caregivers, etc.) about the non-medical aim of the risk calculator.



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**Choice of the screening instrument for the screening program**:

According to Wilson & Jungner all screening instruments and their selected measurements should adhere to the following six domains:[52]

1. **Validity:** The screening instrument should demonstrate high sensitivity and specificity. Sensitivity is the likelihood that the screening instrument correctly identifies individuals who have the condition (true positives). Specificity is the likelihood that the screening instrument correctly identifies individuals who do not have the condition (true negatives).
2. **Reliability:** Selected screening instrument should be highly sensitive.
3. **Yield:** The efficiency of the screening instrument. This refers to the number of cases identified whose prognosis is improved as a result of their early detection. This must be related to the total number of tests performed. In practice, this has to be balanced against the costs.
4. **Cost:** Selected screening instruments should be cost-effective, i.e. investment in the screening should overcome the long-term economic impact of disease. It is good also to consider non-financial impacts such as quality of life.
5. **Acceptance:** The offered screening instrument should be acceptable for the population group offered, i.e. measurements should not be unpleasant for participants as this may decrease their acceptability.
6. **Follow-up services:** For screening of early detection of diseases or their risk factors, there needs to be existing care pathways for individuals identified to be at risk or having a disease.

**The rest of this chapter will discuss how to choose the screening instrument, whether it is a risk prediction tool or a (non-)clinical measurement tool, for your specific screening initiative.**

[52] Wilson JMG, Jungner G. Principles and practice of screening for disease. Geneva: World Health Organization; 1968. Public Health Papers 34. Available from: https://iris.who.int/handle/10665/37650



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*Risk prediction tools in screening*

Risk prediction tools can play an important role in the prevention of CVD (including both coronary and cerebrovascular events) and T2D. When used as screening instruments, these tools can allow for the early detection of individuals at increased risk of developing CVD and T2D, enabling healthcare providers to offer tailored prevention programmes involving healthier lifestyles, pharmacological treatments, other healthcare interventions, and reducing risk factor prevalence (e.g. smoking).[53] These tools use multivariable algorithms to estimate risk and prognosis by integrating patient characteristics, clinical signs, and laboratory tests. **Their primary goal is to prevent CVD and T2D by delivering timely and appropriate interventions to the right persons**. These tools also **facilitate physician decision-making** and promote shared decision-making to **improve patient motivation and adherence**.[54] Research showed that using risk prediction tools increases physicians' awareness of outcomes, understanding of risk factors, and positive attitudes toward preventive management.[55]

**Risk prediction tools are usually developed with two main objectives, (1)** to **assist healthcare professionals** in their clinical decision-making process and **(2) to inform individuals** about their risks of developing an outcome.[56]

- **From a healthcare perspective**, risk prediction tools optimize clinical decisions by ensuring proper risk stratification, preventing overtreatment in low-risk individuals and undertreatment in patients with increased risk. This improves resource allocation, minimizes unnecessary side effects, and enhances patient outcomes.
- **From a patient's perspective**, these tools help individuals understand their risk, empowering them to engage in shared decision-making and make informed choices about prevention strategies. Studies have shown that using risk prediction tools increases physicians' awareness of outcomes, improves understanding of risk factors, and fosters more positive attitudes toward preventive care.

For effective treatment and prevention of CVD and T2D, **clinicians should personalize counseling based on each patient's experiences and circumstances**. This approach encourages patients to commit to improving their health, with a focus on realistic goals, addressing past challenges, and involving patients and families in decision-making. **Risk prediction tools can raise awareness about risk and potential benefits of prevention**. Additionally, involving a team of healthcare professionals (doctors, nurses, psychologists, nutrition experts) **can enhance patient care and outcomes**.[56]

[53] Cooney MT, Dudina A, D'Agostino R, Graham IM. Cardiovascular risk-estimation systems in primary prevention: do they differ? Do they make a difference? Can we see the future? Circulation. 2010;122:300-10.
[54] Kappen TH, Van Loon K, Kappen MA, et al. Barriers and facilitators perceived by physicians when using prediction models in practice. J Clin Epidemiol. 2016;70:136-45.
[55] European Society of Cardiology (ESC). How to use risk prediction tools in daily practice [Internet]. [cited 2025 Jan 15]. Available from: https://www.escardio.org/Education/ESC-Prevention-of-CVD-Programme/Risk-assessment/how-to-use-risk-predictions-tools-in-daily-practice
[56] Rossello X, et al. Risk prediction tools in cardiovascular disease prevention: A report from the ESC Prevention of CVD Programme led by the European Association of Preventive Cardiology (EAPC) in collaboration with the Acute Cardiovascular Care Association (ACCA) and the Association of Cardiovascular Nursing and Allied Professions (ACNAP). Eur Heart J Acute Cardiovasc Care. 2021;9(5):522-30. Available from: https://academic.oup.com/ehjacc/article/9/5/522/6125643


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Challenges in risk prediction tool implementation:

Barriers to routine use include time constraints, clinician skepticism toward simple algorithms, and the variety of available models for the same outcome. Despite these challenges, using risk prediction tools can enhance clinicians' decision-making, improve patient outcomes, and reduce unnecessary treatments, costs, and side effects.[56]

Why a decision guide is needed:

Choosing the most appropriate risk prediction tool is not always straightforward. With a wide array of tools available, each varying in its target population, included risk factors, and geographical validation, the process can become complex. To make informed decisions, healthcare policymakers and practitioners must consider their country/region's unique characteristics, including demographic data, resource availability, and health system infrastructure.

A standardized guide for selecting a CVD and T2D risk prediction tools can therefore prove useful. Such a guide ensures that regions can align their prevention strategies with the most suitable tools, tailored to their specific needs. This not only improves the accuracy of risk assessments but also supports the development of effective public health interventions and policies. WHO HEARTS already includes a decision guide for CVD risk prediction.[57]

The decision guide included in this document provides an updated, stepwise approach to choose the right risk prediction tool for both CVD and T2D. By following the outlined steps, policymakers can select tools that align with their region's population, data availability, and screening goals. This decision guide draws inspiration from a report published by the ESC Prevention of CVD Programme led by the European Association of Preventive Cardiology (EAPC) in collaboration with the Acute Cardiovascular Care Association (ACCA) and the Association of Cardiovascular Nursing and Allied Professions (ACNAP),[56] integrated and merged with the experience of researchers conducting population-based longitudinal studies for elaborating and implementing CVD and T2D risk prediction tools.

[57] World Health Organization. HEARTS technical package for cardiovascular disease management in primary health care: risk-based CVD management. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO. ISBN: 978-92-4-000136-7 (electronic version), 978-92-4-000137-4



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**Step 1: Identify the target population**

**Choosing the right risk prediction tool begins with identifying your primary target groups**. This could include:

- An apparently healthy population (without known CVD or T2D).
- People with existing CVD or T2D.

These primary target groups can be refined using in- and exclusion criteria accounting for age range (young, middle-aged, elderly), ethnicity or race, socioeconomic status, family history, medical history (see step 2), smoking status,... Refining the target population not only helps select an appropriate risk calculator but also ensures accurate risk interpretation and treatment decisions. For example, some calculators adjust for ethnicity or are specifically validated for elderly populations, while others may include additional clinical parameters for high-risk subgroups.

Why target population matters:

CVD and T2D risk prediction tools are designed based on population-specific risk factors and baseline CVD and diabetes risk. Most tools focus on healthy individuals, using risk functions derived from longitudinal epidemiological studies. Risk functions allow us to study the relationship between risk factors and the development of disease. The validity of the use of these functions depends on the population they were designed for and the characteristics of the individuals to which they are applied.

Risk functions are characterized by three main elements:

- the average of the risk factors in the population,
- the risk coefficients, that is, the etiological weight of the individual factors, and
- the probability of the population to survive without the disease.

The first and the third characteristics vary from population to population, and across populations and generations, while risk coefficients tend to remain stable.[58]

Current practice involves predicting 10-year fatal and non-fatal CVD events in individuals without existing CVD. Several risk algorithms are used globally, such as SCORE in Europe, QRISK in the UK, and the ASCVD Risk Calculator in North America. These tools help assess an individual's 10-year CVD risk, influencing decisions on initiating or intensifying medical treatments. All identified risk prediction tools for type 2 diabetes involve identifying individuals at risk of developing the disease within the next few years or up to a 10-year time frame in the general healthy population.

Different guidelines, such as the 2021 European Guidelines on cardiovascular disease (CVD) prevention and the 2024 WHO global monitoring guidance for diabetes prevention and control, classify individuals into risk levels (low, moderate, high, and very high) based on predicted 10-year risk or standardized health indicators.

[58] Progetto CUORE. Manual of the training course of the CVD risk assessment-Progetto CUORE [Internet]. [cited 2025 Jan 15]. Available from: https://www.cuore.iss.it/eng/training/course



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As an example, in the case of CVD (fatal and non-fatal myocardial infarction and stroke), the SCORE2 risk stratification is based on age-specific thresholds, four clusters of countries (low, moderate, high, and very high CVD risk) that are grouped based on national CVD mortality rates. To estimate a person's 10-year risk of total CVD events, one must first identify the correct cluster of countries and the accompanying risk table for their sex, smoking status, (nearest) age, person's Blood Pressure, and non-HDL Cholesterol. CVD risk assessment is systematically used in a stepwise approach of treatment to reach prevention goals.[56]

Even though main guidelines on Diabetes prevention and management (i.e., 'Guidance on global monitoring for diabetes prevention and control' from WHO 2024[59] and the Consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD))[60] mostly focus on prevention and control of related risk factors, diabetes risk assessment tools, based on simple indicators (sex, age, ethnicity, familiarity, physical activity, anthropometric measures, blood pressure treatment), are available.

[59] World Health Organization. Guidance on global monitoring for diabetes prevention and control: framework, indicators and application. Geneva: World Health Organization; 2024.
[60] Zhou B, Lu Y, Hajifathalian K, Bentham J, Di Cesare M, Danaei G, et al. The global burden of diabetes and its complications: an emerging pandemic. Diabetologia. 2018;61(5):1065-1076.



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**Step 2: Review medical history to further define the patient group**

When choosing the right risk prediction tool for a defined target population, the **medical history of individuals in this population is an important factor**. Most tools for CVD risk assessment are designed for healthy individuals without a history of vascular disease. Diabetes risk assessment tools are also provided for healthy individuals (or unaware, at least), but information on family history of diabetes is generally requested as a determinant of risk.

- **Some tools to assess CVD risk include T2D as a single risk factor**, but they do not comprehensively assess the specific risks associated with T2D.
- **For patients with T2D**, CVD-specific tools, like the ADVANCE-risk engine, offer more accurate predictions by considering factors such as HbA1c, albuminuria, retinopathy, and atrial fibrillation. Also SCORE2-Diabetes provides CVD risk estimation in people with T2D in Europe.
- **For patients with a history of vascular disease**, tools like the SMART risk score consider factors like the number of affected vascular sites and kidney function. Tools like the MAGGIC risk calculator and Seattle heart failure model are used for heart failure patients, factoring in variables like NYHA classification and ejection fraction. Some tools also address age limitations, with specific algorithms, such as JBS3 and elderly risk scores, adjusting for competing non-vascular mortality risks in older patients to avoid overestimating CVD risk.
- **For T2D risk assessment**, the QDiabetes Score tool is the only one including also history of CVD (previous heart attack, angina, stroke, or TIA) as a contributing diabetes risk predictor.
- **All identified tools assessing T2D risk require information on the family history of diabetes, instead of personal medical history of CVD.**
- **Five CVD risk assessment tools consider family history of CVD** as a predictor (ASSIGN-SCORE, Swedish NDR risk score, QRISK3, Heart age calculator, Heart Disease Risk Calculator-Cannon Falls), and two out of the T2D risk scores (Leicester Risk Assessment Score and Framingham Diabetes Risk Score).
- **In some cases, risk prediction tools might not be suitable for certain patients**, particularly those with life-limiting comorbidities like advanced cancer, severe pulmonary disease, or end-stage renal disease. Predictions are also less accurate for individuals with extreme risk factors, such as very high cholesterol in familial hypercholesterolemia. [56]

**Step 3: Define the desired risk prediction outcomes**

Establish what you aim to assess with your risk prediction tool:

- **CVD and/or T2D risk:** Are you looking to evaluate the risk of CVD, T2D, or both CVD and T2D?
- **Risk time-frame:** different tools can consider specified time horizons (e.g., 5-year, 8-year, 10-year, or lifetime). Five T2D risk assessment tools do not specify the time frame but focus on risk of having diabetes only.
- **Other risk outcomes:** heart age (in the JBS-3 and in the 'Heart age calculator') and CVD-free life expectancy (in U-prevent). These additional metrics can be easier to explain to patients and are particularly useful for younger individuals, whose 10-year CVD risk is typically low and less specific.[56] For T2D, the RECODe-ASCVD (Risk Equations for Complications Of type 2 Diabetes) is the only scoring system focusing on the whole spectrum of diabetes macrovascular and microvascular complications.



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**Step 4: Consider regional applicability**

When choosing a risk calculator, consider your region, whether Europe, the U.S., Australia/New-Zealand, or elsewhere. Regional differences in lifestyles, environment, genetics, and healthcare systems influence the risk of CVD and/or T2D onsets, impacting the accuracy and applicability of risk prediction tools.

Prioritizing regional validation

To ensure accuracy, select a calculator developed or validated for your specific region. If no such tool exists, consider one validated in a broader but demographically similar area, such as neighboring countries with similar epidemiological profiles. Risk prediction tools must be calibrated to account for geographic and temporal factors in their data sources. This is crucial because lifestyle, environmental factors, genetic backgrounds, and healthcare quality vary across populations, affecting event rates and life expectancy. These differences may not be fully captured by measured risk factors. This is why some countries recalibrate international risk scores, such as the SCORE risk chart or FINDRISC, which have both been validated in many European countries. [56] The WHO CVD risk prediction tool has also been widely validated on a global level, and covers most regions.[61]

In cases where **new risk prediction tools or your preferred risk prediction tool has not been validated for your region or the broader area**, and the only available tools are validated in distinctly different populations, **it is recommended to conduct a pilot validation study**. Testing the risk prediction tool within your specific population helps to assess its accuracy ensures it accurately reflects the risk profiles of individuals in your region, leading to more reliable assessments and effective prevention strategies. **Using an unvalidated risk prediction tool can lead to inaccurate risk estimations, which may affect clinical decisions and public health interventions**. Collaborating with local health authorities or research institutions to validate existing models or develop new ones tailored to your population can significantly enhance the effectiveness of health screening programmes.

[61] World Health Organization. HEARTS technical package for cardiovascular disease management in primary health care: risk-based CVD management. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO. ISBN: 978-92-4-000136-7 (electronic version), 978-92-4-000137-4



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**Step 5: Evaluate available resources and data**

Before selecting a risk prediction tool, evaluate which clinical, laboratory, and lifestyles data you can reliably collect. This includes:

- **Physical measurements** like length, weight and waist circumference
- **Clinical measurements** like blood pressure, height, weight, waist and hip circumferences, BMI.
- **Lifestyle factors** like smoking status, dietary habits and physical activity levels.
- **Laboratory measurements** such as cholesterol levels (total, HDL, LDL), fasting plasma glucose (FPG), Oral Glucose Tolerance Test (OGTT), glycated hemoglobin (HbA1c), and creatinine/eGFR are also important.
- **Other factors** like age, individual and family medical history regarding CVD, T2D and associated risk factors, socioeconomic status, and ethnicity or race.

Some risk prediction tools have features that handle missing or unavailable clinical data, which is common in clinical practice. For example, total and HDL cholesterol may not be measured during initial evaluations. In situations with limited resources, some tools use imputation to estimate average risk factors (for example, total cholesterol and blood pressure in the 'Heart age calculator' from NHS (UK)) or replace lipid measurements with BMI in certain models.[56]

**Step 6: Select the appropriate risk calculator**

**Based on previous steps, you can now select a risk prediction tool that aligns with the target population, regional validation, and available data.** An interactive application to assist users in identifying and selecting risk prediction tools aligned with their specific interests can be found on the JACARDI website https://risktoolapp.shinyapps.io/Risk_Tool/. Consult guidelines (e.g., ESC or ACC/AHA or 2024 WHO Guidance on Global Monitoring for Diabetes Prevention and Control) and refer to the app in order to select tables of tools for each category of interest. For example, for CVD risk tools you can identify QRISK for the UK, SCORE for Europe, and CUORE for Italy. Similarly, the app consents to select also the risk assessment tools related to T2D, such as FINDRISC for Finland, QDiabetes Score for Europe, Type 2 Risk Test for US, and CANRISK for Canada.



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**Step 7: Final considerations before implementation**

After selecting a risk calculator, evaluate additional key factors that may influence its effectiveness in real-world use. This step ensures the tool aligns with clinical guidelines, additional risk factors, treatment impact, usability, and validation needs before implementation:

- **Align with existing clinical guidelines and recommendations:** Guidelines may be less specific for certain populations, such as patients with diabetes, heart failure, or elderly individuals. In these cases, selecting an appropriate tool may require additional clinical judgment or expert consultation.
- **Assess the impact of preventive treatments:** Some risk calculators estimate the individual effect of preventive treatments, which can improve shared decision-making and treatment adherence. Examples include the U-Prevent lifetime tool, which estimates statin or aspirin effects, or the Seattle Heart Failure Model that predicts treatment benefits for heart failure patients. More specifically, SMART-REACH model, DIAL2 model, LIFE-CVD2 model explicitly assess treatment effect related to CVD risk. In none of the identified T2D risk assessment tools, treatment effect is estimated. Indirect effect of treatment can be estimated in the Framingham Offspring Diabetes Risk Score, in which treatment for hypertension is included to estimate T2D risk and in the Cambridge Diabetes Risk Score, in which also 'prescribed steroids', in addition to 'prescribed antihypertensive medication', is included.
- **Evaluate usability and accessibility:** Risk score tools vary in user-friendliness and the timeliness of their interfaces. Many also offer additional features such as language options, personalized guideline recommendations, patient education infographics, and print-out capabilities
- **Incorporate clinical judgement:** Ensure that the chosen risk calculator is used in conjunction with clinical judgment and aligns with local healthcare policies and practices.



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**Clinical and non-clinical measurement methods in screening**:

Clinical parameters such as blood pressure, cholesterol, and blood glucose levels are vital indicators used both independently and within risk prediction tools to estimate an individual's likelihood of developing CVD or T2D.

Traditionally, these parameters are measured in clinical settings by healthcare professionals using standardized methods. However, advancements in technology and a growing emphasis on patient empowerment have paved the way for self-measurement approaches. If self-measurement approaches are deemed to be suitable for screening of populations with increased risk of developing T2D or CVD, this could potentially lead to earlier detection of risk factors. However, with the current evidence, innovative self-measuring devices, as described below, cannot be recommended for screening.

Building upon previous evidence overviews outside of the scope of this short guide, which detailed various methods for measuring these critical parameters, this chapter presents a structured and short guide on the use of clinical and non-clinical measurement methods in screening. The aim is to rank the measurement methods based on their recommended approaches and provide practical guidance for both clinical professionals and individuals performing self-measurements at home.



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*Blood pressure measurement protocols:*

Traditional methods for blood pressure (BP) measurement including the information of preferred devices and validated BP measurement protocol were described outside of the scope of this short guide. In this short guide, information for conducting BP measurement in clinical-settings and BP self-measurement in non-clinical settings is provided. A checklist of what needs to be considered when selecting BP monitors is outlined, and useful references for existing materials are listed.

BP measurement protocols and recommendations for BP monitors are introduced e.g. by the European Society of Cardiology,[62] European Society of Hypertension (ESH),[63,64] and American Heart Association.[65] Furthermore, WHO (2020)[66] has provided guidance and specifications for automated BP devices and proper technique for BP measurement.

There are global hypertension practice guidelines available by the International Society of Hypertension (ISH)[67] including BP measurement protocols, both for clinical and non-clinical settings. The EHES guideline[68] offers comprehensive information on fieldwork procedures including BP measurement protocols in survey setting. Clinical and non-clinical measurement protocols are mostly similar with only slight differences in the protocols. The following table summarizes the details of clinical and non-clinical BP measurement protocols:[67, 69]

| **Clinical/office BP measurement and non-clinical/home BP measurement** | |
|---|---|
| Prerequisites: | No smoking, caffeine, or exercise for 30 min., empty bladder |
| Position: | Person seated comfortably for 3-5 min. in a quiet environment, back, feet and arm supported, and no talking during and between the measurements |
| Monitor: | A validated electronic (oscillometric) upper-arm cuff BP monitor, the instructions by the manufacturer closely followed |
| Placement of measurement arm and cuff: | Arm bare and resting, mid-arm and cuff at the heart level, cuff size selected based on the arm circumference |
| Measurement protocols: | *In clinical protocol:* 3 measurements 1-2 min. apart; an average of the measurements or the last two measurements monitored. Further measurements taken if the readings differ by >10 mmHg. |

[62] European Society of Cardiology (ESC). 2024 ESC guidelines for the management of elevated blood pressure and hypertension [Internet]. 2024 [cited 2024 Nov 11]. Available from: https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/Elevated-Blood-Pressure-and-Hypertension

[63] Mancia, G., Kreutz, R., Brunström, M., Burnier, M., Grassi, G., Januszewicz, A., ... & Kjeldsen, S. E. (2023). 2023 ESH Guidelines for the management of arterial hypertension The Task Force for the management of arterial hypertension of the European Society of Hypertension: Endorsed by the International Society of Hypertension (ISH) and the European Renal Association (ERA). Journal of hypertension, 41(12), 1874-2071.

[64] European Society of Hypertension (ESH). Stride BP [Internet]. 2025 [cited 2025 Apr 3]. Available from: https://www.eshonline.org/communities/working-groups/stride-bp-accurate-bp-monitors/

[65] American Heart Association (AHA). Home blood pressure monitoring [Internet]. 2024 [cited 2024 Nov 11]. Available from: https://www.heart.org/en/health-topics/high-blood-pressure/understanding-blood-pressure-readings/monitoring-your-blood-pressure-at-home

[66] World Health Organization. WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff. World Health Organization; 2020. Available from: https://iris.who.int/handle/10665/331749. License: CC BY-NC-SA 3.0 IGO.

[67] Unger T, Borghi C, Charchar F, et al. 2020 International Society of Hypertension global hypertension practice guidelines. J Hypertens. 2020;38(6):982–1004. https://doi.org/10.1097/HJH.0000000000002453

[68] Tolonen H, editor. EHES Manual. Part B. Fieldwork procedures. 2nd ed. National Institute for Health and Welfare; 2016. Directions 2016_14. URN:ISBN:978-952-302-701-5. Available from: http://urn.fi/URN:ISBN:978-952-302-701-5

[69] McEvoy JW, McCarthy CP, Bruno RM, et al. ESC Guidelines for the management of elevated blood pressure and hypertension: Developed by the task force on the management of elevated blood pressure and hypertension of the European Society of Cardiology (ESC) and endorsed by the European Society of Endocrinology (ESE) and the European Stroke Organisation (ESO). Eur Heart J. 2024;45(38):3912–4018. https://doi.org/10.1093/eurheartj/ehae178



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| | |
|---|---|
| | *In non-clinical protocol:* 2 measurements each time, 1-2 min. apart (i.e., four measurements altogether). Measurements taken twice a day (morning and evening) for at least 3 and ideally 7 days. Measurements taken before drug intake if treated. Measurements recorded and average presented to clinician. |
| Arm selected: | *In clinical protocol:* Measure in both arms at the 1st visit<br>*In non-clinical protocol:* Both arms can be used |
| Other measurements: | *In clinical protocol:* Heart rate and arrhythmia exclusion by pulse palpation. Orthostatic hypotension at the 1st visit, later based on symptoms. |



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*Blood pressure categories and recommendations*

Recommended BP levels differ based on whether the measurement is conducted at office, at home (HBPM), or by means of ambulatory blood pressure measurement (ABPM). In Europe, besides categories set by the ESC and ESH, there are national recommendations for BP which should be referred to if a country-specific information is of interest. BP levels and categories are used for diagnosing and monitoring purposes. Furthermore, the classification of office BP and definition of hypertension grades are presented by ESH.[70,71]

An ideal BP for adults, systolic blood pressure (SBP) falls under 120 mmHg and diastolic blood pressure (DBP) under 80 mmHg. However, a normal BP is regarded as less than 130 mmHg (SBP) and 85 mmHg (DBP). It is known that BP increases with age, and elevated BP is common in middle-aged and older persons. An elevated BP is a risk factor for CVD, and it can be effectively treated with lifestyle modifications. If BP is not very high, lifestyle modifications are initiated first, however, the higher the BP the faster the medication is prescribed. In hypertension, with the help of the medication, SBP is aimed to be lowered under 135 (or 140) and DBP under 85 mmHg.[72] The following table shows examples of the ESC and ESH categories[70,71] for BP levels when different measurement settings are considered:[69]

| | **Normal, non-elevated BP** | **Elevated BP** | **Hypertension** |
|---|---|---|---|
| BP measurement in office settings: | SBP <120 mmHg and DBP <70 mmHg<br><br>SBP 120-129 mmHg and DBP 80-84 mmHg (ESH)<br><br>High-normal: SBP 130-139 mmHg and/or DBP 85-89 mmHg (ESH) | SBP 120-139 mmHg or DBP 70-89 mmHg | SBP ≥140 mmHg or DBP ≥90 mmHg<br><br>Grade 1 hypertension: SBP 140–159 mmHg and/or DBP 90–99 mmHg<br><br>Grade 2 hypertension: SBP 160–179 mmHg and/or 100–109 mmHg<br><br>Grade 3 hypertension: SBP ≥180 mmHg and/or DBP ≥110 mmHg (ESH) |
| HBPM: | SBP <120 mmHg and DBP <70 mmHg | SBP 120-134 mmHg or DBP 70-84 mmHg | SBP ≥135 mmHg or DBP ≥85 mmHg |
| ABPM: | daytime SBP <120 mmHg and daytime DBP <70 mmHg | daytime SBP 120-134 mmHg or daytime DBP 70-84 mmHg | daytime SBP ≥135 mmHg or daytime DBP ≥85 mmHg |

[70] Mancia, G., Kreutz, R., Brunström, M., Burnier, M., Grassi, G., Januszewicz, A., ... & Kjeldsen, S. E. (2023). 2023 ESH Guidelines for the management of arterial hypertension The Task Force for the management of arterial hypertension of the European Society of Hypertension: Endorsed by the International Society of Hypertension (ISH) and the European Renal Association (ERA). Journal of hypertension, 41(12), 1874-2071.
[71] European Society of Hypertension (ESH). Stride BP [Internet]. 2025 [cited 2025 Apr 3]. Available from: https://www.eshonline.org/communities/working-groups/stride-bp-accurate-bp-monitors/
[72] The Finnish Medical Society Duodecim. Elevated blood pressure (in Finnish) [Internet]. [cited 2025 Jan 22]. Available from: https://www.terveyskirjasto.fi/dlk00034/kohonnut-verenpaine-verenpainetauti?q=verenpaine



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*BP monitors*

A mercury sphygmomanometer combined with the auscultatory Korotkoff sound technique, conducted by a trained health care professional, has traditionally been regarded as the gold standard for BP measurement. Evidence is increasingly showing that this technique can result in misclassification of many persons as hypertensive, and masked hypertension is not detected as readings in clinical settings may be normal whereas they can be elevated outside the clinic. Furthermore, the use of mercury is nowadays banned, and mercury devices have been phased out in clinical settings.[73,74] Nowadays, BP measuring devices using oscillometric technique are generally regarded as benchmark devices. The validated devices undergo independent validation process by an established protocol. Validation protocols of BP monitors performed by the following stakeholders are considered reliable:

- Association for the Advancement of Medical Instrumentation (AAMI)
- European Society of Hypertension International Protocol (ESH)
- International Organization for Standardization (ISO)
- British Hypertension Society (BHS)
- European Society of Hypertension International Protocol (ESH-IP).

STRIDE BP as an international and scientific organization by hypertension experts has launched criteria for evaluation of validation studies including BP monitors. Since the start of 2024, new validation studies should apply the AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018) and its Amendment 1, 2020-01. STRIDE BP recommends only monitors with cuffs including office, home, and ambulatory monitors. For the monitor to be validated, at least one STRIDE BP approved validation study should be published over the last 10 years by using the protocols by AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018), ANSI/AAMI/ISO 2013 or 2009, or ESH-IP 2010. For home monitors, automated storage of multiple measurements or mobile phone, PC, or internet connection for data transfer and objective reporting should be available. STRIDE BP follows a checklist for each validation study by considering study population, sample size, selection criteria, device type, cuffs, and pass/fail criteria. STRIDE BP has listed preferred devices to be used.[75,76] When selecting a suitable monitor, the following checklist could be of help:

- A monitor needs to be clinically validated and verified to be accurate.[69]
- Lists of validated monitors are provided by both international and national organizations such as STRIDE BP (https://www.stridebp.org/) and American Medical Association (AMA) (https://www.validatebp.org/).
- Automatic, cuff-style, upper arm monitors are recommended.[65,75]
- Wrist and finger monitors are not recommended due to less reliable readings.[65]

[73] Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals: Part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. Hypertension. 2005;45(1):142–161. https://doi.org/10.1161/01.HYP.0000150859.47929.8e

[74] Ogedegbe G, Pickering T. Principles and techniques of blood pressure measurement. Cardiol Clin. 2010;28(4):571–586. https://doi.org/10.1016/j.ccl.2010.07.006

[75] Stride BP. About STRIDE BP. Validated devices listing – Principles and procedure [Internet]. 2025 [cited 2025 Feb 3]. Available from: https://www.stridebp.org/about-us/principles-for-device-listing/

[76] Stergiou GS, Alpert BS, Mieke S, et al. Validation protocols for blood pressure measuring devices in the 21st century. J Clin Hypertens (Greenwich). 2018;20(7):1096–1099. https://doi.org/10.1111/jch.13294



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*Novel, innovative monitors*

Besides so-called traditionally used BP measuring devices, there are new innovative methods and devices available, either already on the market, or in development. WHO (2020)[66] has introduced some of the new methods of BP measuring, not requiring external pressure (by a cuff), however with the caution of inadequate evidence on the accuracy of these devices. The methods listed in the first row of the following table are undergoing testing and development processes, and before they can be used for screening or monitoring purposes, the devices should be validated and certified. The second row of the table introduces different stakeholders providing validation and certification. Additionally, devices should have a CE mark to be suitable to be used for medical purposes. Currently, the accuracy of most of the innovative devices is questionable, and the innovative methods included in the table below can be recommended only for complementary measuring. The table provides an overview of the details to be considered when investigating novel BP measuring devices *(information from the different websites of the manufacturers)*:

| | |
|---|---|
| Method/technique: | • Oscillometric BP measurement at the wrist level<br>• Photoplethysmography (PPG) integrated in smartphone applications or smartwatches<br>• Electronic/wireless BP monitor with Wi-Fi synchronization<br>• Electrocardiography (ECG) monitor with Wi-Fi synchronization<br>• PulseRead technology, pulse wave combined with a single-lead ECG<br>• Pulse transit time (PTT)<br>• Pulse wave analysis (PWA) |
| Validation/certification/recommendations: | • STRIDE BP<br>• Protocol of the American National Standards Institute (ANSI)<br>• Association for the Advancement of Medical Instrumentation (AAMI) standards<br>• Protocol of the European Society of Hypertension (ESH)<br>• International Organization for Standardization (ISO)<br>• CE mark for medical devices<br>• Clinically validated<br>• Recommendations e.g. by cardiologists |
| Measurement protocols: | • Method- and device-specific, and instructions provided by the manufacturer should be followed |
| Advantages: | • Easy-to-use devices<br>• Often small, cuffless, and clock-like devices<br>• Wide availability of smartphones and Wi-Fi-connections<br>• Multiple and on-demand measurements<br>• Can include BP, heart rate, and ECG measurements<br>• Data uploading possibilities to PC or smartphone |
| Disadvantages: | Variations in:<br>• evidence on validity, accuracy, and reliability between methods and devices<br>• certification and calibration aspects<br>• evidence- and theory-basis<br>• availability between countries<br>• position and movement specifics for accurate measures |



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*Cholesterol measurement protocols:*

Blood lipids such as total cholesterol (TC), high-density cholesterol (HDL), low-density cholesterol (LDL), and triglycerides (TG) are normally taken and analyzed from venous blood samples, and this is regarded as the gold standard for cholesterol measurement. It should be acknowledged that the laboratories measuring cholesterol need to follow the protocols of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and Clinical and Laboratory Standards Institute (CLSI). Furthermore, testing and protocols should be conducted in an accredited laboratory environment following the standards of the International Organization for Standardization (ISO). In addition, it is common for national professional associations to regulate the protocols for testing to ensure that the gold standard measurements are followed. Therefore, both international and national standards should be closely inspected when implementing cholesterol measurements.

Clinical cholesterol testing protocol includes either a simple blood test taken from the arm or a finger-prick test. However, only the measurement taken from the arm can be recommended for screening purposes as well as for diagnosing, since finger-prick method does not adequately comply with the accuracy requirements provided by the gold standard measurement. The following table introduces the protocol of cholesterol measurement from the arm:[77,78]

| | **Venous blood from the arm:** |
|---|---|
| Prerequisites: | • **May or may not** require fasting (8 to 14 hours) before testing (drinking of water is allowed). According to current knowledge, fasting for lipid measures is not needed, and non-fasting lipid profiles can better predict harmful CVD outcomes. The evidence is inconsistent, however.<br>• Whether fasting is required it is determined by the doctor, and advice from the doctor should be carefully followed (too long fasting can affect the results)<br>• If fasting is required, testing is recommended to be done in the morning<br>• Prescribed medicines can be taken normally before testing |
| Positions and other requirements: | • Adequate lighting in sampling point is needed<br>• Person tested is sitting in a sturdy chair, preceding 10-15 min. of rest, sleeve rolled up, and arm resting on a cushion<br>• If a person faints easily during the blood collection, a sample can be taken in supine posture<br>• Blood is usually drawn from the left arm, a tourniquet is used |
| Measurement protocols: | Blood is drawn from the arm with a needle. The blood sample is sent to the laboratory, and the results are normally received within the same day. |
| Assays taken: | TC, HDL, LDL, and TG. LDL can be measured either directly or by using TC, HDL, and TG (if TG levels are below 4.5 mmol/L). |

[77] National Health Service (NHS). Getting tested – High cholesterol [Internet]. 2024 [cited 2024 Nov 26]. Available from: https://www.nhs.uk/conditions/high-cholesterol/getting-tested/

[78] Fimlab. Fat examination and cholesterol measurement [Internet]. 2024 [cited 2024 Nov 26]. Available from: https://fimlab.fi/en/services/fat-examination-and-cholesterol-measurement-fp-kol-fp-kol-hdl-fp-kol-ldl-fp-trigly



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*Novel, innovative devices*

Innovative protocols and devices are available nowadays for cholesterol measurement in home-settings. There are many brands and devices available, some of them use liquid blood and some dry blood spot samples (DBS). These tests can be easy-to-operate, cost-effective, and quick. Instructions from the manufacturer should be carefully followed for successful measurements. Some devices, even though designed for non-clinical use and self-measurement purposes, are only sold for professionals. Furthermore, mistakes in test result interpretation poses an ethical problem when a non-clinician operates them. Although there are blood collection devices to be used in home-settings, the information regarding the parameters measured is often lacking. A possibility for blood cholesterol analysis is mentioned only in a few devices. If cholesterol is included, it is limited to TC and HDL values, and if LDL and TG are calculated, the results are less reliable.

Concerns for using the novel cholesterol measuring devices include questionable accuracy and reliability. There are gaps in validation processes and acceptability, diagnostic performance, and certification of the devices. It is important to note, that the ESC guidelines recommend the analysis of a lipidogram from plasma blood in a clinical setting. The National Health Service (NHS) allows screening in general practitioners (GP) office and pharmacies if a standard laboratory is difficult to access. In some countries implementation in an accredited laboratory environment is required. This raises the need for further critical reflection on the accuracy and usability of point-of-care testing (POCT) in non-clinical settings.

Given the current knowledge, self-measurement devices cannot be recommended for screening purposes, and self-measuring of cholesterol should never replace a doctor`s visit.

There are various companies, who manufacture self-measuring devices, and when selecting a monitor, the following site could be of help '*U.S. Food & Drug Administration (FDA) – Approved Home and Lab Test*'.



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*Glycemia-related measurements:*

Blood glucose-related (BG) measurements are fundamental tools in the screening, diagnosis, and management of diabetes. Accurate measurement of blood glucose-related measures allow for the identification of individuals at risk of developing diabetes, diagnosis, and monitoring of disease progression and/or treatment effectiveness. Several methods exist for measuring blood glucose-related parameters, each with varying levels of accuracy, convenience, and applicability in different clinical settings.

Hyperglycemia is not only a hallmark of diabetes but also a significant risk factor for cardiovascular diseases (CVD). Chronic hyperglycemia contributes to vascular damage, increasing the likelihood of atherosclerosis, hypertension, and other cardiovascular complications. This link between diabetes and CVD underscores the importance of screening for hyperglycemia in identified individuals at increased risk of developing T2D, followed by interventions to prevent long-term complications.

Types of glycemia-related measurements:

The most commonly used types include fasting plasma glucose (FPG), glycated hemoglobin (HbA1c), and the oral glucose tolerance test (OGTT).[79,80] In **screening**, **FPG or HbA1c are mostly used**, but their limitations need to be strongly considered, having in mind the low concordance of the result among the two. As for the **diagnostic** test, **OGTT** remains the most sensitive procedure),[79] followed by **FPG and HbA1c**. In addition, HbA1c below the diagnostic threshold does not exclude diabetes. Therefore, several international recommendations and guidelines suggest different approaches, that are then even more adapted at national level while adapting to the availability of the respective diagnostic method.

Blood glucose can be measured through **different sample acquisition methods**. The two primary types are **capillary blood glucose (CBG) and venous plasma glucose (VPG)**. **Capillary blood glucose**, obtained via a **fingerprick**, is commonly used for **self-monitoring** but is **less accurate** than laboratory-based venous blood tests. **Venous plasma glucose**, collected from a vein and analyzed in a laboratory, is the **golden standard for clinical diagnosis due to its higher accuracy**. **Continuous glucose monitoring (CGM),** which measures **interstitial glucose levels** using a sensor, is **primarily used for diabetes management rather than screening or diagnosis**. While CGM provides near real-time glucose trends, its readings exhibit a significant time lag compared to blood glucose levels, particularly during rapid fluctuations. As a result, CGM values do not correspond directly to blood glucose levels. CGM is **not yet validated for use in screening or diagnostic context**.

[79] Cowie CC, Rust KF, Byrd-Holt DD, Gregg EW, Ford ES, Geiss LS, et al. Prevalence of diabetes and high risk for diabetes using A1C criteria in the U.S. population in 1988–2006. Diabetes Care. 2010;33(3):562–8.
[80] Selvin E, Wang D, Matsushita K, Grams ME, Coresh J. Prognostic implications of single-sample confirmatory testing for undiagnosed diabetes: A prospective cohort study. Ann Intern Med. 2018;169(3):156-64.



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*Most common glycemia-related measurement methods are introduced in following table:*[81]

| | **Capillary blood glucose:** | **Venous plasma blood glucose:** | **Glycated Hemoglobin (HbA1c)** | **CGM:** |
|---|---|---|---|---|
| **Measurement taken from:** | Fingertip, earlobe, heel, forearm, palm | Vein (typically arm) | Vein (typically arm) | Sensor on back of the upper arm or abdomen |
| **Pre-requirements:** | No pre-requirements unless testing fasting glucose | Fasting required (8+ hours) for FPG, OGTT requires glucose load | No pre-requirements | No pre-requirements |
| **Equipment:** | A lancet to prick the skin<br>a glucometer<br>test strips | Laboratory equipment for venous blood sample analysis | Laboratory equipment for HbA1c sample analysis | A water-resistant disposable sensor<br>a reader to scan the sensor |
| **Clinical or non-clinical settings:** | Clinical- or non-clinical settings | Clinical settings, sample analyzed in accredited laboratory | Clinical settings, sample analyzed in accredited laboratory | non-clinical settings |
| **Outcomes measured:** | Instant blood glucose level (fasting or non-fasting) | Fasting plasma glucose (FPG), OGTT, or random plasma glucose (RPG) | It reflects average blood glucose over the past 8-12 weeks and has the strongest link to the risk for chronic complications | Current interstitial fluid glucose level and glucose trends |
| **Advantages:** | Capillary blood glucose testing is less painful than venous sampling, requires only a small blood sample, allows alternative site testing if supported by the glucometer, and provides immediate results. | Gold standard for diagnosis (most accurate and standardized method) | No fasting or special preparation needed<br>Reflects long-term glucose control | Continuous tracking of glucose levels<br>Alarms for hypo-/hyperglycemia<br>No finger pricks required for newer models |
| **Disadvantages:** | Capillary blood glucose testing can be costly due to expensive test strips, which may not always be accurate, and results can vary in reliability, often requiring calibration with test strips | Venous plasma glucose is a slightly painful, invasive procedure<br>not suitable for frequent sample collection | HbA1c is not useful for detecting acute glucose changes, is less sensitive than FPG for early diabetes detection, and may be inaccurate in conditions affecting red blood cells, such as anemia or chronic kidney disease (CKD). | Some older CGM devices may require calibration with finger-prick tests<br>glucose is not detected in the interstitial fluid as rapidly as in blood (with capillary samples) which may hinder the reliability<br>the costs of sensors and readers |

[81] Mathew TK, Zubair M, Tadi P. Blood glucose monitoring. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan– [updated 2023 Apr 23; cited 2025 Jan 31]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK555976/



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The most recent official report on diabetes provided by WHO includes current WHO recommendations for the diagnostic criteria for diabetes and intermediate hyperglycaemia (WHO, 2016).[82] Glycemia-related diagnostic criteria are introduced in the following table.[73, 83]

| Test Type | Normal | Intermediate Hyperglycemia (IFG/IGT) | Diabetes |
|---|---|---|---|
| **Fasting Plasma Glucose (FPG) (requires at least 8 hours of fasting)** | <100 mg/dL (<5.6 mmol/L)<br><br>< 110 mg/dl (< 6.1 mmol/L) still officially used in many Member States | 100[84]-125 mg/dL (5.6-6.9 mmol/L)<br>110-125 mg/dl (6.1-6.9 mmol/L) still officially used in many Member States | ≥126 mg/dL (≥7.0 mmol/L) on two occasions |
| **HbA1c** | <5.7% (<39 mmol/mol) | 5.7-6.4% (39-47 mmol/mol) | ≥6.5% (≥48 mmol/mol) on two occasions |
| **Oral Glucose Tolerance Test (OGTT) (2h post-load)** | <140 mg/dL (<7.8 mmol/L) | 140-199 mg/dL (7.8-11.0 mmol/L) | ≥200 mg/dL (≥11.1 mmol/L) |
| **Random Blood Glucose (RBG) (Only for symptomatic cases)** | - | - | ≥200 mg/dL (≥11.1 mmol/L) + symptoms |

Novel, innovative devices:

**FPG, HbA1c and OGTT are most used for diabetes screening and diagnosis**, and alternative methods, even though explored, have still not proven to compare to the gold standard method. Due to the shortcomings in accuracy and reliability, **new devices and methods can only be recommended as complementary measures and not substituting established glycemia-related measurement**. These methods include e.g., advancing technology of CGM and the sensors used for measuring glucose values. Optical technologies, such as spectroscopy, used in sensors could offer a solution for non-invasive measures as glucose could be measured through the skin without a need of needle pricks. Furthermore, increasing amount of smartphone and -watch, and other device applications are available for glucose monitoring. Glucose levels can also be measured in other bodily fluids than blood, e.g. using of sweat is explored by applying wearable devices including patches and temporary tattoos. In addition, some other examples of biological fluids under development include saliva, tear fluid, urine, and mucus from respiratory organs.

**However, at this stage, given the incomplete processes of development of these novel devices and methods, including e.g., validation, accuracy, standardization of techniques, and deciding on the reference values, self-monitoring of blood glucose (SMBG) cannot be regarded as a screening method for pre-diabetes or diabetes.**

[82] World Health Organization. Global report on diabetes. World Health Organization; 2016. Available from: https://www.who.int/publications/i/item/9789241565257.
[83] World Health Organization (WHO). Mean fasting blood glucose [Internet]. 2025 [cited 2025 Jan 31]. Available from: https://www.who.int/data/gho/indicator-metadata-registry/imr-details/2380
[84] The cut-off value for impaired fasting glucose (IFG) has been subject to ongoing discussions among various Member States. While some regions previously used 6.1 mmol/L (110 mg/dL) as the lower threshold for IFG, current alignment efforts with WHO recommendations suggest maintaining a cut-off of 5.6 mmol/L (100 mg/dL) where possible. For further reference, see WHO Indicator Metadata Registry.


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## JACARDI suggestions on screening activities and establishing a centralized screening governance platform for CVD and T2D

JACARDI strongly recommends that relevant health authorities **establish a centralized platform to oversee all aspects of screening programmes for CVD and T2D**. Such a platform should provide a **structured framework for informed decision-making** across the entire screening process, including assessing and adapting screening programmes based on outcomes, ensuring effective communication with the public, target populations, and healthcare professionals, and providing strategic leadership for screening initiatives.

Within this broader platform, a **dedicated component for risk prediction tools** would enable countries to select tools that are scientifically validated and suited to their specific populations and healthcare contexts. To maintain accuracy and relevance, third-party developers should be able to apply for the inclusion of their risk calculators, committing to regular updates and quality assurance through an accountability agreement.

**This short guide provides the basis for this platform**, following the steps outlined in the chapter "Deciding on the implementation of screening activities". This chapter provides templates on how to create a governance structure, map stakeholders, conduct a situational analysis, review existing evidence, evaluate recommended screening initiatives according to relevant screening criteria. These steps have also been brought together in the template for evaluating the design of a screening programme (Appendix "Template for evaluating the design of a screening programme").

**Practical guidance** on how to implement, monitor and evaluate your screening initiative, as well as guidance on roadmapping and ensuring sustainability for your screening initiative, **will be provided in upcoming JACARDI publications.**

By integrating these functions into a comprehensive oversight mechanism, health authorities can facilitate best practice sharing, promote standardization in risk assessment methodologies where possible, and ensure that screening programmes remain evidence-based, adaptable, and transparent.

**A centralized resource of this nature would enhance collaboration and innovation within the global health community, ultimately strengthening prevention strategies and improving health outcomes for CVD and T2D worldwide**.



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# Appendix – Template for evaluating the design of a screening programme

## Title of the screening programme (Provide a concise title for the screening programme, and add a version identification)

*This comprehensive template not only ensures that all critical aspects of a screening programme are addressed but also facilitates meaningful discussions with expert groups and stakeholder boards. In regions where screening initiatives are governed by local or national authorities or third-party expert organizations, the completed template can be submitted to the relevant parties for thorough review and evaluation, promoting informed decision-making and alignment with regional health policies.*

## Administrative information

*This is an optional part of the document, useful when decisions on whether or not to implement a screening programme are made by governing bodies that are not necessarily the same as the organizer of the screening programme.*

| Category | Details |
|---|---|
| **Title of the Screening programme** | |
| **Country / Region** | |
| **Name of the organizing Organization / Institution** | |
| **Contact Person** | |
| **Address** | |
| **Phone Number** | |
| **Email** | |
| **Website (if applicable)** | |
| **Legal Entity Type** | |
| **Proposed Start Date of the screening programme** | |
| **Proposed End Date of the screening programme (if applicable)** | |

*Executive Summary*

*(Max 600 words. Summarize the key details of the proposal, including the target condition, population, screening test, expected benefits, and implementation plan.)*

**Region *X* is planning to implement a national/regional screening programme to ... (*e.g. identify their population at increased risk of cardiovascular disease (CVD) and/or type 2 diabetes (T2D)*). The initiative aims to ... (*e.g. combine a risk assessment tool with targeted clinical follow-up and structured lifestyle guidance programmes*). Expected benefits include ... (*e.g. improved early identification of high-risk adults, reduced incidence of cardiometabolic events, and strengthened links between prevention, primary care, and data monitoring*). This programme will be tested in a pilot project, which will be evaluated for feasibility, cost-effectiveness, and population acceptability before nationwide roll-out.**



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## Wilson and Jungner criteria checklist

In 1968, Wilson & Jungner[85] published criteria set of principles to be used when making decisions to set up new screening programmes. These principles can help determine whether a screening programme is likely to be an effective or cost-effective intervention. To consider screening, a particular disease should comply with following principles:

| | **Does the condition to be screen comply with following principles?** | **Y** | **N** |
|---|---|---|---|
| 1 | The disease sought should be an important health problem. | | |
| 2 | There should be an accepted treatment for patients with recognized disease. | | |
| 3 | Facilities for diagnosis and treatment should be available. | | |
| 4 | There should be a recognizable latent or early symptomatic stage. | | |
| 5 | There should be a suitable test or examination. | | |
| 6 | The test should be acceptable to the population. | | |
| 7 | The natural history of the disease, including development from latent to declared disease, should be adequately understood. | | |
| 8 | There should be an agreed policy on whom to treat as patients. | | |
| 9 | The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care. | | |
| 10 | Case-finding should be a continuing process and not a "once and for all" project. | | |

Use this checklist to evaluate whether the condition you want to screen for, is suitable for screening.

## Governance structure

*Outline the key players that will actively partake in creating and governing the screening programme (programme director, scientific advisory board, expert group composition, etc.).*

| **Governance Structure** | | | |
|---|---|---|---|
| **Role** | **Name Surname/initials only** | **Institution** | **Comments** |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

[85] Wilson JMG, Jungner G. Principles and practice of screening for disease. Geneva: World Health Organization; 1968. Public Health Papers 34. Available from: https://iris.who.int/handle/10665/37650



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## Stakeholder analysis

*Identify the key stakeholders (individuals, institutions or organizations that in any way may show interest for the screening programme, or are affected by the screening programme, or are important advocates for continuation and potential scalability of the screening programme). They can come from different fields and distinct expertise and experience (healthcare, education, research, communication and ICT technology, NGOs, patients' associations and civil society). They may differ in their interest and their power. Specifically, those with high interest and high power should be closely involved as early as possible. They will also constitute stakeholders' board, that will be actively involved in the design of the screening programme.*

| **Key stakeholders and their level of involvement** | | | | |
|---|---|---|---|---|
| **Institution/person (Initials)** | **Contact known yes/no*** | **Position on screening programme**** | **Level of involvement***** | **Comments** |
| **Government & Public Authorities** | | | | |
| *Ministry of Health* | | | | |
| *National Institute for Public Health* | | | | |
| *Regional/Local Health Departments* | | | | |
| *Ministry of Economics/Finance* | | | | |
| *Municipalities & Local Authorities* | | | | |
| *Public Health Agencies/ Governmental Health Authorities* | | | | |
| **Healthcare Professionals & Associations** | | | | |
| *Primary Care Physicians (GPs)* | | | | |
| *Nurses* | | | | |
| *Cardiologists, Endocrinologists, Diabetologists* | | | | |



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| | | | | |
|---|---|---|---|---|
| *Professional Organizations & Medical Associations* | | | | |
| **Academia & Research Institutions** | | | | |
| *Universities & Public Research Institutions* | | | | |
| *Independent Researchers & Research Networks* | | | | |
| **Social-Profit Organizations (Patients & Professionals)** | | | | |
| *(Inter)national/regional CVD Organizations* | | | | |
| *(Inter)national/ regional Diabetes Organizations* | | | | |
| **Civil Society & Community Groups** | | | | |
| *Community Groups, Religious Communities & Local Initiatives* | | | | |
| *Food Banks/Social Support Organisations* | | | | |
| **Population & End-Users** | | | | |
| *End-users/People with or at risk of CVD or T2D* | | | | |
| *Populations living in vulnerable situations (migrants, people with disabilities, elderly, low-income, minority groups)* | | | | |
| **(Health) Insurance Providers** | | | | |
| *Health Insurance Companies* | | | | |
| **Workforce & Trade Unions** | | | | |
| *Workforce & Trade Unions* | | | | |
| **Media Services** | | | | |
| *Media (general or health-specific) Representatives* | | | | |



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| **Educational Services** | | | | |
|---|---|---|---|---|
| *School System/Educational Institutions* | | | | |

* contact details should be known to screening programme governance; here, report just yes (known) or no (not known yet)
** strong support, moderate support, neutral, moderate opposition, strong opposition
*** level of involvement:

- full participation; the stakeholder may even be included to governance structure;
- consultation; the stakeholder will be actively consulted during screening programme design;
- informed; (1) the stakeholder will be fully informed on the progress of the screening programme; or (2) the stakeholder will be only briefly informed during usual screening programme communication and dissemination activities.



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## Situational analysis

*The situational analysis helps to determine whether screening is (still) an appropriate strategy or whether an early diagnosis programme might be preferable. This analysis looks at the problem description (description of the disease, its natural evolution, and burden of disease), whether primary preventive strategies have already been implemented effectively, comprehensive control plans exist for T2D and/or CVD, and core components of early diagnosis and high-quality treatment of symptomatic people has been optimized.*

*Disease and Public Health Relevance*

Epidemiology & Significance

- Describe the disease's natural course, including the average time from onset to symptoms, spontaneous remission rates, and progression.
- Explain known risk factors and early indicators.
- Provide key data on disease prevalence, trends, and impact, focusing on the region for screening implementation where possible.
- Demonstrate the burden on public health (incidence, mortality, morbidity, survival, quality of life).
- Compare with international data.
- Summarize key arguments for why this disease is a public health priority.

Early Detection & Risk Factors

- Identify primary prevention measures in the region for screening implementation and compare with international efforts.
- Identify current screening efforts in the region for screening implementation and compare with international efforts.
- Identify early detection efforts based on symptoms in the region for screening implementation and compare with international efforts.
- Identify available treatments in the region for screening and their effectiveness.

**If all relevant information on epidemiology and significance can be provided, if sufficient efforts have been made concerning primary prevention & early detection, and if there is sufficient availability of treatment, this can indicate that a screening approach may be warranted.**

**If screening may be considered the right course of action, the evidence related to screening must be examined in detail.**



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## In-depth evidence review

*This in-depth review of evidence will cover effectiveness and cost-effectiveness for possible screening approaches, using the GRADE framework. This evidence review will result in:*

- **A table summarizing all relevant studies on effectiveness, cost-effectiveness, harms and benefits associated with screening programme:** author, country, year of publication, study type, study population, intervention studied, comparison group, results, potential biases, conclusions, web link to publication (if you start a new in-depth evidence review);
- **A table summarizing all relevant international guidelines on relevant screening programmes** (if you use an existing evidence-review).

Following the GRADE framework, gathered evidence will be graded based on its quality, yielding evidence-based recommendations or guidelines that policy-makers and researchers can adhere to:

| Recommendations | Class of recommendation[a] | Level of evidence[b] | Relevant studies[c] |
|---|---|---|---|
| **Topic of recommendation** | | | |
| X | I, IIa, IIb, III | A, B, C | xx, yy, zz,... |
| Y | I, IIa; IIb, III | A, B, C | xx, yy, zz |

A – class of recommendation
- Class I: Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective. → Is recommended or is indicated
- Class II: Conflicting evidence and/or divergence of opinion about the usefulness/efficacy of the given treatment or procedure.
  - IIa: weight of evidence/opinion is in favour of usefulness/efficacy → should be considered
  - IIb: Usefulness/efficacy is less well established by evidence/opinion → may be considered
- Class III: Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful → is not recommended

B – level of evidence
- Level A: Data derived from multiple randomized clinical trials or meta-analyses.
- Level B: Data derived from a single randomized clinical trial or large non-randomized studies.
- Level C: Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

C – relevant studies
- Add references for relevant studies on which the recommendations are mainly based

**If the evidence review recommends or highlights specific screening approaches for CVD and T2D, these recommended or highlighted approaches should be used as a foundation to construct new screening programmes, or as a benchmark to compare with existing screening approaches in the region. The screening design for your region should then be further evaluated.**



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## Evaluation of the screening design

*This part of template serves as a practical tool for screening programme initiators to outline the essential components of their programme design. It guides users through defining measurable objectives, identifying the appropriate target population, selecting and evaluating screening instruments, establishing effective follow-up pathways, and assessing the legal, financial, and ethical dimensions of the program.*

*Programme objectives*

6.1.1 Define objectives of the screening programme with measurable targets (e.g., desired incidence reduction, mortality reduction, early-stage detection increase, quality-of-life increase, health outcome improvement,...)
6.1.2 Provide key performance indicators based on expected outcomes.
6.1.3 Compare screening effectiveness with alternative prevention strategies.

*Target Population*

6.2.2 Characteristics:
- Specify inclusion criteria (e.g., age, gender, socio-economic status, lifestyle, location, work, etc.)
- Explain why this population is the most suitable for screening.
- Identify all high-risk subgroups and justify their inclusion/exclusion.

6.2.3. Recruitment:
- Describe strategies to recruit, identify, and invite eligible individuals.
- Address potential barriers to participation and describe efforts to mitigate this.
- Analyze whether subgroups or certain vulnerable populations may be less reached and propose corrective measures.


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*Screening Instrument*

- **Description & Performance**
  - Provide details on the screening test (method, technology, safety).
  - Outline key performance metrics (sensitivity, specificity, false positive/negative rates, predictive values).
  - Justify the choice of this instrument compared to available alternatives.
- **Application & Feasibility**
  - Describe how and when the screening test is implemented.
  - Address availability, required resources, and capacity for large-scale implementation.
  - Address quality assurance, standardization, and monitoring measures.
  - Specify screening frequency and re-testing criteria.
  - If the screening strategy involves stepwise screening (subsequent use of multiple screening tests), please elaborate.
  - If the screening strategy involves multiple screening (use of different screening tests in the same screening visit), please elaborate.
- **Result Interpretation & Follow-up Pathways**
  - Define thresholds for abnormal vs. normal results, including any intermediate categories.
  - Provide the expected distribution of screening results in the target population.
- **Acceptability & Burden of the screening instrument**
  - Assess acceptability among the target population (cost, risks, emotional burden).
  - Consider acceptability for healthcare professionals (training, workload, applicability).
  - Provide an assessment of the expected screening instrument-related benefits vs. harms.
  - Describe measures to optimize participant experience and minimize negative impacts.



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*Follow-up, Diagnosis & Treatment*

- **Value of Early Intervention**
  - Demonstrate improved outcomes with early treatment or intervention.
  - Provide evidence from meta-analyses, systematic reviews, or RCTs.
  - Discuss net health benefits, weighing advantages and potential harms (e.g., overdiagnosis, unnecessary treatments) for participants with positive and negative screening results e.g., in terms of quality of life, relative five- or ten-year survival rates, or life expectancy—absolute or in healthy life years).
- **Diagnostic & Follow-up Pathways**
  - Outline clinical pathways for positive and negative screening results, including next steps such as diagnostic confirmation procedures and referrals.
  - Demonstrate availability, accessibility, and quality of diagnostic tests, treatments and other meaningful health actions after a positive screening result for the target population.
  - Address risks of overdiagnosis, overtreatment, and their impact on quality of life.
  - Ensure coordination between screening, diagnostics, and treatment.
  - Describe administrative and clinical integration strategies.

*Communication & Stakeholder Engagement*

- Outline strategies for informing healthcare providers and ensuring coordinated efforts.
- Describe pre-screening communication efforts (outreach, invitations, informed consent).
- Explain post-screening communication (result notification, support for positive/negative cases, complaints,...).

*Organization, Data Flow & Implementation*

- Map the participant pathway through the screening process.
- Describe required infrastructure, workforce, etc.
- Define task distribution among stakeholders.
- Describe the (centralized) information system for tracking screening data.
- Explain data-flow within the screening programme, and describe how to engage in effective data management and reporting.
- Describe quality monitoring and how adjustments will be made if issues arise.
- Describe any required preconditions (reimbursement, etc.), as well as the responsible parties.
- Identify potential implementation barriers and facilitators for the organization, data flow an implementation of the screening programme.



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*Acceptability of the screening programme as a whole*

- Assess acceptability among target groups, healthcare professionals, policymakers and society.
- Address additional ethical concerns, including informed decision-making and equity issues.
- Provide an overall assessment of the expected benefits vs. harms.
- Describe measures to optimize participant experience and minimize negative impacts.
- Consider how societal attitudes toward screening may impact participation.

*Legal & Regulatory Framework*

- Ensure compliance with regulations (EC certificate, MDR, GDPR, etc.).
- Describe how screening aligns with national and international guidelines.

*Financial & Resource Assessment*

- Provide a cost estimate, including funding sources and budget allocation.
- Assess resource availability (staff, infrastructure, expertise).
- Address financial sustainability and long-term feasibility.
- Model the expected cost-effectiveness of the screening programme based on regional information.
- Provide a simulation of the screening programme feasibility: operational readiness (ensuring quick access to all levels of screening) and evaluation of current and missing resources, including cost estimates

*Monitoring & Evaluation*

- Define how the screening programme will be monitored, including process and impact evaluation.
- Define how the screening programme will be updated according to evaluation results.
- Ensure transparency through public reporting and ongoing review.
- Provide plans for addressing challenges as they arise.

*Summary*

- Summarize key arguments supporting the proposed screening programme.

## Next Steps & Pilot Testing

**If applicable, outline steps for piloting before full implementation. Pilot testing contributes to a better understanding of feasibility, resource implications and optimal delivery strategy in a certain region.**



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