

MedTech Europe Cardiovascular Sector Group Policy Proposals for the EU Cardiovascular Health Plan

# 30/30 EU CVH Plan: Reducing CVD mortality by 30% in 2030

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Cardiovascular diseases (CVDs) remain the **leading cause of mortality and disability in the European Union** (EU), accounting for approximately 1.7 million deaths in 2021, which represents 32.4% of all deaths. Today, some 60 million Europeans are living with CVD, this is more than the whole of Italy. CVD is also the leading cause of death in women and linked to huge inequalities across geography and socio-economic status too.

The prevalence of CVDs is anticipated to rise due to factors such as an aging population and increasing prevalence of risk factors like obesity, hypertension, and diabetes. Stroke alone is the leading cause of disability and the second leading cause of death worldwide. Projections indicate a significant increase in CVD prevalence and mortality by 2050, underscoring the urgent need for proactive measures. Beyond the profound personal loss, CVDs impose a substantial economic burden. The total cost of CVD to the EU economy surged from €210 billion in 2017 to €282 billion in 2021 — an increase of 34.3% in just four years. iii,iv This includes €155 billion in healthcare and long-term care costs, €79 billion attributed to informal care provided by family and friends, and €47 billion due to productivity losses from illness, disability, and premature death. These figures underscore the significant strain CVD places on healthcare systems and the broader economy.

Medical technologies play a central role in the fight against CVD, delivering lifesaving and life-improving innovations that enhance patient outcomes while alleviating financial and operational pressures on healthcare systems. With CVD costing 11% of total EU health expenditure, high-quality medical technologies can contribute significantly to cost containment and efficiency gains. As an example, for stroke specifically, recent breakthroughs in prevention and treatment bring potential to cut the burden of stroke in half.

These innovations span the entire patient journey, from early detection and diagnosis to referral, treatment and quality of life and overall they reduce the economic and social burden. For instance, blood tests that identify patients with high cholesterol, high risk of heart attack, and heart failure facilitate early intervention, preventing expensive emergency care and late-stage complications. Modern imaging devices that detect arterial narrowing enable earlier, more targeted treatments, reducing the need for costly invasive interventions. Small cardiac implants such as pacemakers, defibrillators, and trans-

catheter technologies help prevent cardiac events, reducing emergency hospital admissions and long-term disability costs. Minimally invasive heart valve and ballon/stent procedures improve clinical, procedural, and patient outcomes and reduce hospitalization times, lower complications, and decrease recurrence rates. Implantable cardiac monitors and associated home monitoring solutions allow for remote patient management, detection of asymptomatic events, minimizing unnecessary hospital visits and easing the burden on healthcare professionals.

Addressing the increasing burden of CVDs demands coordinated action at the EU level. The MedTech Europe Cardiovascular Sector Group, a co-founder and partner of the European Alliance for Cardiovascular Health (EACH), therefore strongly welcomes the 3rd December 2024 adoption of Council Conclusions on the Improvement of Cardiovascular Health in the EU and the European Commissioner's commitment to adopting a European Cardiovascular Health Plan on the same day.vi

Building on these commitments to tackle the burden of Europe's leading cause of death, the new EU Cardiovascular Health Plan should contain clear objectives, and concrete and ambitious actions that will tangibly improve people's cardiovascular health and quality of life, reduce the burden of CVD and including stroke, by improved access to detection, referral, treatment and rehabilitation.



From an innovative medical technology industry perspective, the European Commission has a unique momentum to work on the launch of the EU Cardiovascular Health Plan, and suggests a **launch within one year of the adoption of the Council Conclusions, on 3rd December 2025**. This will acknowledge the EU commitment to tackling the CVD burden, and accelerate access for patients in urgent need.

The CVH Plan should contain a <u>clear overall objective</u> of reducing premature and preventable CVD-related deaths and disabilities<sup>vi</sup> by 30% by 2030 and extending years in good health. This is in line with the UN Sustainable Development Goals 3.4.<sup>vii</sup>

To achieve this objective, the CVH Plan should prioritize 4 specific actions to drive equitable patient access across the care continuum, in addition to the already ongoing work on prevention of non-communicable diseases and invest smartly to support strong EU coordination and support Member States in effectively reducing the burden of CVDs for patients, their families, the healthcare system, wider society and the economy.

1. Optimize Patient Pathways from Early Detection, Diagnosis up to Referral and Treatment: Promoting early detection and timely diagnosis of cardiovascular disease is fundamental to improving outcomes and reducing hospitalizations and long-term care needs. A European cardiovascular health check program should be established to ensure systematic screening of at-risk individuals and enable timely referral to specialist care. This must include targeted screening efforts for women, who remain underdiagnosed and undertreated, through gender-sensitive approaches and awareness initiatives. To maximize impact, early detection efforts must be supported by well-defined EU guidelines for referral pathways and integrated care models to tackle current variability in standards and fragmented referral processes across Member States, complemented by quality and assurance schemes as exists in the European Beating Cancer Plan, and looking at stroke.viii

- 2. Set an EU Network of Cardiovascular Centers as national and regional hubs of excellence: Ensuring equitable access to effective cardiovascular interventions and reducing time to treatment is critical to lowering mortality and improving quality of life. To do so, a European Network of Comprehensive Cardiovascular Centers should be set up, developing standards to support strengthened infrastructures, and integrating multidisciplinary care delivery. Tackling healthcare workforce shortages through the integration of technological and procedural innovations that reduce the CV burden. Special attention must also be given to gender disparities, with a task force focused on ensuring that women receive equal access to care.
- 3. Support real-time, evidence-based making, as well as strengthened understanding of disease burden and treatment efficiencies: To ensure and support real-time and evidence-based decision-making, a European CVH Knowledge Centre should be set up, fast-tracking the EU deployment, and integration of existing cardiovascular registries (e.g. SWEDEHEART), and ensuring data harmonization and accessibility in alignment with the European Health Data Space. The EU CVH Knowledge Centre could be in charge of monitoring and assessing the EU CVH Plan implementation and execution with publicly available KPIs and yearly objectives and milestones. A dedicated CV Inequalities Registry should be developed to focus on fostering more understanding and support to action to tackling inequalities in gender, geography, and generations.
- 4. A Strong EU Innovation Access Policy tailored to CV needs, and strengthening competitiveness: To achieve tangible reduction of CVD burden, the EU must urgently act to ensure patients have more accelerated access to medical devices innovation through more efficient and timely evidence development, regulatory, economic and value assessment, investments, and procurement pathways. This will mean using existing economic cost-benefit evidence to guide investment decisions, ensuring smoother transitions from early feasibility studies to accelerated regulatory access, adaptive health technology assessments, improved value-based procurement systems, and streamlined reimbursement and funding mechanisms.

The ambition of a new EU CVH Plan to reduce the CVD burden by tackling mortality and improving quality of life will only be reachable, if the EU <u>invests smartly</u> into its execution. **5 Billion EUR over a period of 5 years** – *less than 2 % of the actual annual economic burden of CVD* – should be landmarked to implement the CVH Plan, and support Member States in their efforts to improve equitable access to detection, referral, treatment, and leveraging the potential of MedTech CV breakthrough, AI, digital, precision medicine innovations to improving efficiencies, reducing burden on hospitals and healthcare workers, and the healthcare system. The EU CVH Plan should also be **measurable and trackable with clear KPIs** and governance, allowing for transparent and structured engagement of all relevant CV stakeholders.

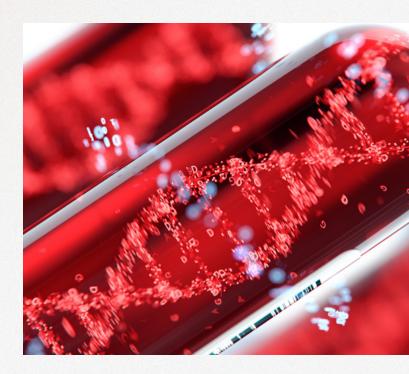
# Our Specific Policy Proposals For The EU CVH Plan

POLICY PROPOSAL 1: Optimise Patient Pathways from Early Detection and Diagnosis to Referral and Treatment to improve patient outcomes

Preventing, detecting, and diagnosing cardiovascular conditions early – and managing them efficiently when they occur – is essential to keeping citizens of all ages out of the hospital and in good health, while making efficient use of healthcare resources. Improving secondary prevention in only seven European countries (France, Germany, Italy, Spain, Denmark, Poland, and the UK) could prevent over 670.000 CVD deaths over the next ten years: the EU could leverage so much more benefit from medical technologies to tackle the burden of CVD.

As indicated in the Council Conclusions of December 2024, the European Commission "should facilitate discussion on better ways to promote systematic screening" and Member States should "scale up secondary prevention through evidence-based cardiovascular health checks that incorporate timely screening, early detection and precision diagnostics tailored to diverse population needs".x

Implementation: A European Cardiovascular Health Check Program should be established to ensure early detection and precision diagnosis, with a clear goal of reaching a percentage of at-risk individuals screened for CVD. This could include targeted screening for key cardiovascular risk factors such as blood pressure, cholesterol levels, BMI, PAD, and enable age-appropriate risk assessments, and heart health checks across diverse populationsxi. Evidence shows that heart checks are not routine across the European population, leading to huge under-detection even in the at-risk population. A third of respondents to a 2019 European survey of people aged over 60 said their primary care physician checked their heart with a stethoscope "occasionally"; only 28% had their heart checked at every visit.xii



Leveraging the full spectrum of medical technologies, considered should be (digital) stethoscope checks, blood tests and CV biomarkers, in-vitro diagnostics (IVDs), echocardiography, early detection hand-held devices, and data-driven and Al tools. Thanks to innovative medical technologies, this screening would facilitate timely interventions that improve outcomes and reduce long-term healthcare costs.

By integrating precision medicine and digital/Al health solutions screening effectiveness can be enhanced, whilst reducing healthcare burdens, and optimizing patient outcomes. By incorporating digital tools that support patient preparation for later interventions and

recovery post-treatment, this program would ensure a continuum of care that maximizes efficiency and patient well-being.

The European Cardiovascular Health Check Program can learn and benefit from the experience and organisation already in place for other screening programs such as cancer, as these programs have shown to save lives and improve quality of life.xiii

Whilst early detection is a critical component to ensure that citizens are more aware and have an earlier opportunity to enter the care pathways, reaching the objectives of a 1/3 reduction in mortality and disability by 2030, will only be achieved with more effective cardiovascular referral, treatment and after-care.

This will therefore require strong action to facilitate well-coordinated, optimized and evidence-based care pathways that ensure patients receive the right care, in the right setting, with the right teams, and at the right time. This means overcoming the current

to invest in comprehensive multidisciplinary training programs for reskilling healthcare professionals on cardiovascular and stroke care, especially within primary care and amongst specialist nurses. Funding can be secured from the EU Health Programs, Research Framework Programs, and Cohesion Funds within the Multiannual Financial Framework.

To ensure that patient pathways will be tailored to the needs of patients, especially those impacted by inequalities, a dedicated focus should be brought to understanding and tackling these.

The set-up of a **dedicated task force on inequalities** – supported by an Inequalities Registry managed by the Joint Research Centre - should actively come up with **specific actions and recommendations to contribute to closing the inequality gaps, especially in women**, in access across the pathway, including gender-sensitive protocols in screening and with attention to the impact of inequalities in poor access and management of CVD, leading to amputations for



fragmented referral processes and uneven standards of care across and within Member States and between CVDs themselves, which are causing to delays in treatment, poorer outcomes, and inefficiencies in healthcare delivery.

Implementation: The European Commission should introduce an initiative to either develop, or facilitate the implementation of existing, European guidelines on optimal CVD and stroke pathways and a quality assurance scheme to define a common set of requirements for cardiovascular and stroke services to improve the quality of care.xiv The EU could support Member States at national and regional levels

some CVDs.xv It should also make recommendations about reducing inequalities in access to prevention and treatment across EU Member States.

# POLICY PROPOSAL 2: Set-Up an EU Network of Comprehensive Cardiovascular Centres

Lack of investments, inefficiencies in hospital infrastructures and broader healthcare system challenges impact substantially optimal treatment and care of CVD patients. Urgent improvements are needed to ensure stronger coordination, and stronger efficiencies in healthcare delivery, and ensuring health professionals build the skills for the future.

This is especially relevant as healthcare workforce shortage remains a major challenge, impacting waiting times for common elective CV surgeries, which remain high in most OECD countries.\*\*vi Medical technology innovations can help release health systems' capacity and enable better care for more patients with existing resources. Such technologies can alleviate the burden of work on healthcare professionals, enhance patient outcomes leading to reduced hospitalisations, ultimately improving outcomes, efficiency and effectiveness and strengthening the resilience of the healthcare systems. Their potential needs to harness and they need to be considered as part of the solution to reducing the CVD burden.

Inspired by the success of the European Reference Networks (ERNs) and the model established under Europe's Beating Cancer Plan, the European Commission should therefore create a network of Comprehensive Cardiovascular Centres (CCCs) as national and regional hubs of excellence, based on population needs and national infrastructures – and co-funded through EU4Health and Cohesion Funds.xviii
This network would build on existing efforts such as accredited stroke units.

Implementation: These centres would help to improve outcomes by anchoring structured, multidisciplinary care and ensuring better coordination across care settings. CCCs would also strengthen continuity of care, facilitate equal patient access to timely and effective treatment, and support professional development and knowledge exchange. By integrating care delivery, education, and data, they would contribute to long-term improvements in cardiovascularand stroke health across the EU.



#### Core responsibilities could include:

- Developing and applying evidence-based protocols for detection, intervention, treatment, and rehabilitation.
- Ensuring timely patient referral and treatment, with shared care models connecting hospitals, primary care, and specialist services.
- Providing multidisciplinary care through integrated teams including cardiologists, nurses, rehabilitation specialists, and digital health experts.
- Serving as national hubs for training and continuous professional development.

- Collecting and reporting standardised outcome data to inform the to-be set up EU Cardiovascular and stroke Registry and support benchmarking and health system improvement.
- Ensure the network facilitates knowledge exchange and best practice sharing, including through regular collaboration with the Cardiovascular Health Knowledge Centre and other EU-supported networks.
- Prioritise equity by ensuring geographical distribution of CCCs includes underserved and remote areas, and by integrating gendersensitive care models into their service delivery frameworks.







# Policy Proposal 3: A CVH Knowledge Centre to support real-time decision-making

Reaching the objectives of reducing the burden of CVD, including stroke, with reducing mortality rates and improving quality of life in an equal manner, will also require strong real-life data and evidence. This is critical to allow for real-time and evidence-based policy, decision-making and guidelines development to standardize and optimize care delivery and reduce inequalities in detection and treatment.

Implementation: The set-up of an EU Cardiovascular Health Knowledge Centre - in alignment with the European Health Data Space (EHDS) and coordinated by the Joint Research Centre - could serve as the central hub to accelerate the uptake and use of real-world data, facilitate the rapid integration of disease registries, and support data-driven policymaking and prioritization. Taking into consideration interoperability challenges, the Centre should fast-track the EU deployment, and integration of existing cardiovascular registries (e.g. SWEDEHEART EuroHeart), and ensure data harmonization and accessibility.

The EU CVH Knowledge Centre will be in charge of monitoring and assessing the EU CVH Plan implementation and execution with publicly available KPIs and yearly objectives and milestones. The CVH Knowledge Centre could also integrate a Cardiovascular and stroke Inequalities Registry, providing an inequalities registry in care across Member States to inform policy decisions and funding allocations.

In addition to data, registries, and quality assurance, the Centre should contribute to research innovation through collaboration with in-silico medicine initiatives, using modelling and simulation tools to complement clinical data and support innovation in diagnostics and treatment planning.

The Centre should also collect and share existing evidence about cost-benefits of specific preventive and treatment options, to enable evidence-based policy making.



# POLICY PROPOSAL 4: Accelerate CV innovation access pathways from early evidence up to procurement and funding/reimbursement

Timely patient access to breakthrough cardiovascular and stroke innovations is limited across Europe due to fragmented regulatory (IVDR/MDR) pathways, barriers to evidence generation, and lack of uptake quality-driven procurement and reimbursement/funding systems. A streamlined and coordinated EU policy approach is needed to reduce delays and ensure that life-saving technologies are effectively integrated into care.

**Implementation:** Adopt a harmonised EU methodology for **Early Feasibility Studies** (EFS), based on the Innovative Health Initiative (HEU-EFS) to support early clinical investigations and facilitate faster, safer access to breakthrough CV technologies.xviii

Introduce **accelerated regulatory pathways** for medical technologies that address unmet medical needs, building on the EU model used for pharmaceuticals, and for innovative devices in other regions of the world, and leveraging the current revision of the Medical Device / IVDR Regulation.xix

Ensure that the implementation of the **EU HTA Regulation** allows for adaptive Joint Clinical

Assessments and supports alignment between

HTA and public procurement to facilitate access to

CV innovations that reduce burden on hospital and
healthcare systems. Reform **EU public procurement frameworks** to support value-based purchasing.

The revision of EU public procurement directive should enable quality-driven procurement processes that reward long-term outcomes and system-level efficiency, rather than lowest-cost criteria. Encourage Member States to adopt quality-driven procurement models, including early dialogue with innovators and co-definition of unmet needs, as part of national cardiovascular strategies. Promote equitable and timely reimbursement of CV diagnostic and therapeutic innovations across Member States by supporting innovative payment models and facilitating the exchange of best practices. Develop and implement evaluation frameworks for digital medical devices (DMDs) that consider real-world effectiveness, broader system value, and long-term benefits to support their uptake and integration into clinical practice.



# Investments And Funding Required

To realise the objectives set above and to concretely reduce the CVD burden, it is essential to include cardiovascular health as a priority within EU funding programmes. We therefore suggest allocating a total of EUR 5 billion over a period of 5 years— which is less than 2% of the current annual CVD burden - to cardiovascular diseases and leveraging multiple EU funding sources to drive access to detection, referral, treatment, to ensure relevant investments in infrastructures, and to support Member States in the adoption and deployment of innovative solutions that improve outcomes. This funding should also support a comprehensive mapping of the disease burden and further research, address gender-specific and inequalities.

Funding for the EU CVH Plan should be strategically leveraged from multiple EU sources, including the current Multiannual Financial Framework (MFF), drawing allocations from the Health Programs, European Regional Development Fund (ERDF) and Cohesion Funds, InvestEU, NextGen EU, and Horizon Europe, including the Innovative Health Initiative, and the Digital Europe Programme. The new Multiannual Framework, including the potential competitiveness, Al and other innovation focused funds, should be leveraged towards the implementation of the EU CVH Plan.

- EU4Health, Innovative Health Initiative, ERDF, Cohesion Funds, Next Gen EU, and Digital Europe could focus on early detection efforts and improvements to be made in the patient pathways and supporting actions in terms of infrastructures and the set-up of the Comprehensive Cardiovascular Centres, reskilling of healthcare professionals, the knowledge centre, as well as the introduction of tailored regulatory, assessment and procurement pathways.
- Invest EU and the future Competitiveness Fund could be deployed to support and co-fund Member States' efforts to accelerate uptake of innovations.
- Overall, funding should prioritise initiatives
  that reduce mortality and disability by enabling
  real-world integration of proven technologies
  and improving care delivery across the EU, as
  well as support breakthrough innovations,
  digital health, Al-powered diagnostics,
  remote monitoring, and precision
  treatments, ensuring that at least 50% of
  funded projects involve tangible uptake and
  health system integration in Member States.



### **KPIs And Governance**

To ensure effective implementation and accountability, a robust governance framework should be established, including mechanisms for monitoring progress, assessing impact, and ensuring stakeholder engagement. This can be achieved through the following measures:

- Establishment of an EU Cardiovascular Monitoring and Coordination Group: A dedicated body, working within the framework of the European Health Union, should oversee the implementation of the Cardiovascular Health Plan. This group should include representatives from the European Commission, Member States, patient organizations, healthcare professionals, relevant industry representatives and research institutions to ensure a multistakeholder approach.
- Stakeholder Engagement and Public-Private
  Collaboration: Industry stakeholders should
  play a key role in supporting innovation-driven
  policy implementation, advising on regulatory
  and technological advancements, and promoting
  public-private partnerships to enhance investment
  in cardiovascular research and innovation. Regular
  multi-stakeholder dialogues should be organized
  to align objectives and facilitate knowledgesharing across Member States.
- Regular Progress Assessments: The
  implementation of the plan should be evaluated
  through annual progress reports that monitor key
  performance indicators (KPIs), such as reductions
  in premature CVD-related mortality and disability,
  improvements in early detection rates, uptake of
  innovative treatments, and reductions in regional
  and gender disparities, with clear target dates.
   Suggested KPI could be as follows.

Strategic Goal	Target	Monitoring Indicators	Target year
Reduction in CVD Mortality and Disability and extend years in good life	30% reduction in premature deaths and disabilities (aligning with UN SDG 3.4)	Mortality rates from CVD and stroke and years in good health	2030
Early Detection, Diagnosis, Referral and Treatment	EU framework for early detection and Council recommendations Increase in early screening rates among women EU guidelines for patient pathways Set Up Coordinated CV Centres allocating primary and comprehensive specialty centers according to national/regional requirements.	% of at-risk individuals receiving annual heart checks, including PAD Increase of women receiving early screening compared % of high-risk individuals receiving specialist referral after initial screening % of diagnosed patients receiving guideline-based treatment within an optimal timeframe Increase in uptake and deployment of innovations that improve outcomes and reduce CVD burden in hospitals and health centres EU network of CV hospitals covering EU member states	2026: - EU framework and Council recommendations - Coordinated CV Centres set-up 2027: - Pathways guidelines
Innovation Access	Accelerated regulatory pathways for CV Innovations, Adaptive HTA, Uptake of Quality-Driven Procurement and Reimbursement models  Set up of Knowledge Centre to enable real-life decision making and understanding of burden, inequalities, and gaps in patient pathways	MDR /IVDR inclusion of accelerated pathways, adaptive HTA deployed, new Procurement Directive includes Quality-Driven Procurement for CV Health Technologies Active Knowledge Centre with accelerated uptake of registries	2026: - MDR revision includes accelerated pathways - Adaptive HTA deployed  2027: - EU PPD includes quality driven CV and stroke technologies  2028: - Active CV Knowledge centre
Investments and Funding for Innovation	€5 billion of total budget allocation earmarked for CVD leveraging multiple EU funding sources.	Total EU funding directed at CVD.	2025 for overall budget allocation

# About MedTech Europe and the Cardiovascular Sector Group

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions. The MedTech Europe Cardiovascular Sector Group represents the Cardiovascular Medical Technology Industry, which provides solutions to the burden of CVD on individuals, families and the wider society and economy.

Medical technologies play a central role in the fight against CVD. These innovations, which span the full spectrum of patient care from diagnosis to cure, save lives and add tremendous value to European society. High quality medical technologies are central to Europe's quest for better cardiovascular health and can be found throughout the patient journey, for instance: the blood tests that identify patients with high cholesterol, high risk of heart attack and heart failure; the modern imaging devices that detect narrowing of the arteries, mechanical thrombectomy that can significantly reduce mortality and disability from stroke; the small cardiac implants such as pacemakers, defibrillators and trans-catheter technologies; the implantable cardiac monitors and associated home monitoring solutions; the minimally invasive heart valve and stent procedures that improve clinical, procedural and patient outcomes, while reducing associated costs and recurrence.

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# Case Studies

# MedTech Europe Cardiovascular Sector Group: Case studies

# Policy Proposal 1: Optimise Patient Pathways from Early Detection and Diagnosis to Referral and Treatment to Improve Patient Outcomes

#### Early Detection of Heart Failure through Biomarkers<sup>i</sup>

**Situation:** In Spain, the burden of undiagnosed and late-diagnosed heart failure cases contributed to delayed treatment initiation and avoidable hospitalisations. General practitioners lacked standardised tools to rule out heart failure early, in addition to the increased workload as a result of late diagnoses.

**Strategy:** The Spanish National Primary Care Portfolio included NT-proBNP testing as a routine diagnostic tool across all 17 autonomous communities. The measure aimed to enable early identification of heart failure at the primary care level.

**Impact:** The implementation of the testing enabled the rule-out of heart failure and may lead to a reduction of echocardiography referrals by up to 40% and a 25% decrease in specialist cardiac clinic referrals. Diagnosis and treatment times could be cut nearly in half, while the hospitalisation and mortality rates for patients diagnosed in primary care may drop by up to 50%.

#### Expanding Access to Life-Saving Stroke Treatment<sup>ii</sup>

**Situation:** Mechanical thrombectomy for acute ischemic stroke, a highly effective minimally invasive procedure where a blood clot is removed from a vessel, typically in the brain or heart, to restore blood flow, remain underutilised in the EU, with fewer than 7% of eligible patients receiving it in 2019<sup>iii</sup>.

**Strategy:** Efforts to increase the adoption of mechanical thrombectomy as a standard intervention for large-vessel stroke, supported by cost-effectiveness and life-saving data, were launched to encourage its broader uptake in stroke care pathways during randomised controlled clinical trials between 2015 and 2019.

**Impact:** The treatment was considered more effective and less costly than standard of care in two-thirds of the countries. Increasing access to thrombectomy to just 15% of eligible patients would improve the lives of 285.000 Europeans. The therapy has proven to generate over 101.000 additional quality-adjusted life years and save up to EUR 1.7 billion in societal costs.<sup>iv</sup>

#### Identifying Aortic Stenosis through Integrated Screening<sup>v</sup>

Situation: Aortic Stenosis (AS) often goes undetected until it reaches a severe stage, particularly in older populations.

**Strategy:** A pilot study in the UK integrated AS screening into influenza vaccination campaigns in primary care settings. The screening also included auscultation and a 2D echocardiography.

**Impact:** The programme identified 18% of patients with a heart murmur and referred 10% for further cardiac evaluation. The approach was projected to identify around 130.000 cases of moderate to severe AS nationwide, validating the effectiveness of integrated screening.

# Screening for cardiovascular risk in the general population – the Scaling-Up Packages of Interventions for Cardiovascular Disease Prevention in selected sites in Europe and Sub-Saharan Africa (SPICES) implementation survey<sup>vi</sup>

**Situation:** Cardiovascular disease (CVD) accounted for 32% of global deaths in 2019.<sup>vii</sup> In France, the rural and medically underserved region of Centre Ouest Bretagne (COB) faces especially high CVD mortality and limited access to primary care. A scalable, low-resource screening approach was needed to identify at-risk individuals without straining already stretched family practitioners.

**Strategy:** As part of the EU-wide SPICES project, non-physician screeners—mainly health students, along with pharmacists and nurses—used the Non-Laboratory Interheart Risk Score (NL-IHRS) and a digital tool to assess CVD risk at public events. Over five months, 3,384 people were screened in Belgium, France, Uganda, the United Kingdom and South Africa. Qualitative interviews with 47 screeners highlighted enablers like strong public engagement, media visibility, and trust in the screening process.

**Impact:** Over half of those screened were identified as having moderate to high CVD risk. The approach preserved physician time, required minimal infrastructure, and proved both cost-effective and easily replicable. Notably, it presents a scalable model for expanding screening within limited budgets while delivering substantial public health benefits. By leveraging trained health students and community-based outreach, the programme achieved broad coverage without placing additional strain on healthcare systems. This aligns with recent EU policy recommendations calling for increased investment in preventive care and innovative population health strategies.

### Cost-effectiveness of population screening for atrial fibrillation: the STROKESTOP study\*iii

Situation: Atrial fibrillation (AF) is a leading cause of stroke in older adults, yet often remains undiagnosed.

**Strategy:** The STROKESTOP study in Sweden targeted individuals aged 75–76, a high-risk group, to assess whether population-based screening for AF could reduce long-term health and economic burdens. In this randomised trial, 27,975 individuals were assigned to either an AF screening invitation or control group. With a median follow-up of 6.9 years, clinical outcomes and health economic data were analysed using a Markov model and probabilistic sensitivity analysis to estimate long-term cost-effectiveness.

Impact: The screening approach proved cost-saving and health-enhancing—delivering 77 life-years and 65 Quality-Adjusted Life Years (QALYs) gained per 1,000 screened, while reducing strokes and overall healthcare costs by €1.77 million. AF screening was cost-effective in 99.2% and cost-saving in 92.7% of scenarios. This study provides the first long-term, randomised evidence supporting AF screening as a dominant preventive strategy in ageing populations.

### Cost-effectiveness of mass screening for untreated atrial fibrillation using intermittent Electrocardiogram (ECG) recording<sup>ix</sup>

**Situation:** Asymptomatic atrial fibrillation (AF) in older adults often goes undetected, increasing stroke risk and long-term healthcare costs. Identifying AF early in high-risk populations, such as individuals aged 75–76, could improve outcomes and reduce system burden.

**Strategy**: This study used a lifelong decision-analytic Markov model to simulate 1,000 individuals mirroring the STROKESTOP population. It evaluated the cost-effectiveness of a two-week intermittent ECG screening programme, factoring in AF prevalence, anticoagulation treatment, stroke risk, and healthcare costs.

**Impact:** Screening led to 263 more patient-years with detected AF, preventing 8 strokes and gaining 12 QALYs and 11 life-years per 1,000 screened. The incremental cost was modest (€50,012), with a cost of just €4,313 per QALY and €6,583 per stroke avoided—demonstrating strong cost-effectiveness. These results support integrating targeted ECG-based AF screening into national preventive care strategies for ageing populations.

#### Early Detection of Cardiovascular Disease in High-Risk Populations<sup>x</sup>

**Situation:** Cardiovascular disease often goes undetected in high-risk populations such as individuals with type 2 diabetes or chronic obstructive pulmonary disease (COPD), due to symptom overlap and fragmented care pathways. In the Netherlands, delayed diagnosis of heart failure, atrial fibrillation, and coronary artery disease contributes to worse outcomes and increased healthcare costs.

**Strategy:** The RED-CVD (REDetecting Cardiovascular Disease) trial tested a pragmatic, low-cost screening approach to improve early detection of cardiovascular disease in high-risk individuals. It focused on patients with type 2 diabetes or COPD —two groups with elevated, often-overlooked cardiovascular risk due to overlapping symptoms. Conducted across 25 general practices in the Netherlands (14 intervention, 11 control), the study enrolled 1,216 adults. The intervention consisted of a three-step strategy: a symptom and risk factor questionnaire, NT-proBNP blood testing (a biomarker for heart failure), a 12-lead ECG to detect rhythm abnormalities, and a physical exam. The primary endpoint was the number of newly diagnosed cases of heart failure, atrial fibrillation, or coronary artery disease after one year. The strategy was integrated into existing chronic disease management programmes and delivered by trained practice nurses under GP supervision.

**Impact:** The proactive strategy more than doubled the detection rate of cardiovascular disease (8% vs 3%) within one year. The method is scalable, affordable, and minimally burdensome, leveraging practice nurses and GP discretion. It holds promise for early intervention, better patient outcomes, and alignment with EU policy priorities on preventive care. A cost-effectiveness analysis is underway to confirm long-term value.

## Generating positive economic and organisational impact by creating efficiency and enhancing healthcare capacity in Italy $^{\rm xi}$

**Situation:** Transcatheter Aortic Valve Implantation (TAVI) has become a standard minimal invasive treatment for patients with symptomatic severe aortic stenosis (SAS). New evidence and guidelines recommend TAVI for an increasing number of patients. Yet at the same time, health care providers are facing capacity constraints (staff availability, intensive therapy beds, and Cath labs) to satisfy this increasing demand. Innovation in process benefits both patients and organisations. This is why the University Hospital of Parma initiated a study to optimise the TAVI care pathway, aiming to improve efficiency, resource utilisation, and patient outcomes.

**Strategy:** A dedicated Pathway Efficiency Programme was developed, tested and validated. The programme fosters a detailed optimisation strategy aimed at improving procedural practices at the hospital, reducing the burden of healthcare workers, whilst ensuring excellent patient outcomes.

**Impact:** In one hospital in Italy, the application of the dedicated programme helped to improve procedural practices throughout the patient pathway in hospital settings (pre-, peri, and post-procedural) and leveraging innovative minimal-invasive medical technologies. This resulted in an average cost reduction of EUR 3,900 per patient treated. In addition, the reduction in length of stays could free up capacity to treat more patients (a total of 112 days in ICCU) – enhancing opportunities for more patients to get access to quality CV care.

# Policy Proposal 2: Set-up an EU Network of Comprehensive Cardiovascular Centres

#### Stroke prevention for Atrial Fibrillation Patientsxii

**Situation:** In England, over 50.000 patients with non-valvular atrial fibrillation (NVAF) are unsuitable for oral anticoagulants and thus remain vulnerable to strokes.

**Strategy:** An evaluation of a national-scale up scenario for Left Atrial Appendage Close (LAAC) therapy through catheter-based procedures within the National Health Services (NHS) care settings was conducted.

**Impact:** Performing 1.000 LAAC procedures annually over three years would prevent 734 strokes and deliver GBP 37 million in savings over a period of 10 years. Broader access to these therapies through regional cardiovascular hubs could institutionalise long-term clinical and economic gains.

#### Cardiac trained first-responder systems<sup>xiii</sup> increase survival in cardiac arrests

**Situation:** Across Europe, survival rates for out-of-hospital cardiac arrest (OHCA) vary widely, with high-performing countries like Denmark showing 55% survival rates compared to near zero in lower-performing Member States (0% in Romania).

**Strategy:** The Netherlands and Nordic countries implemented first-responder systems combining trained volunteers, AED deployment, and emergency alert networks to reduce response times.

**Impact:** Survival increased significantly when early defibrillation occurred within minutes. These systems demonstrated the value of community-integrated cardiovascular emergency protocols that could be scaled via EU cardiovascular centres.

#### Collaborative Cardiology Care for Better Outcomesxiv

**Situation:** Germany's healthcare system struggles with fragmentation between primary and specialist care, particularly in managing chronic cardiovascular (CV) conditions—leading to poor care coordination, late interventions, and high system costs. Cardiovascular disease remains the leading cause of death, underscoring the need for structured, proactive care pathways.

**Strategy:** The Baden-Wuerttemberg collaborative cardiology care programme integrated general practitioners (GPs) and cardiologists under a selective care contract (GP-centered care + cardiology contract). The approach focused on proactive, guideline-based management of patients with heart failure, coronary artery disease, arrhythmias, and valvular conditions. Using shared care protocols, coordinated referrals, and continuous monitoring, the programme shifted care from reactive hospital-based treatment to structured outpatient management.

**Impact:** Among 58,000+ patients, the programme improved treatment quality, reduced emergency visits and hospitalisations, and achieved lower disease-specific costs. Care shifted from reactive to planned, outpatient management. This real-world example shows how proactive, collaborative care not only improves outcomes but also enhances system efficiency—offering a scalable model for chronic cardiovascular disease management.

### **Empowering Primary Care Physicians in CVD Management**\*\*v

**Situation:** Cardiovascular disease is a leading cause of death, yet its management is often fragmented. Primary care physicians (PCPs), despite being the most frequent point of contact for patients, are underutilised in chronic CVD care due to poor communication with specialists, system inefficiencies, and lack of coordination—compromising continuity and outcomes.

**Strategy:** Positioning PCPs as central players in proactive CVD management involves improving collaboration with cardiologists, enhancing information flow (e.g., shared notes, direct communication), and empowering PCPs to monitor risk factors, adjust treatment, and support lifestyle changes. Integrating PCPs into multidisciplinary teams and guideline development fosters more consistent, long-term management of CVD.

**Impact:** Greater PCP involvement leads to better risk factor control, earlier interventions, improved transitions of care, and reduced hospital use—particularly in heart failure and coronary disease. Though cost data are limited, stronger PCP engagement is consistently linked to improved patient outcomes and is key to building scalable, proactive care models in cardiovascular health.

#### Spain's Model for Equitable Access to Specialised Cardiovascular Carexvi

**Situation:** Spain's National Health System faced disparities in access to specialised cardiovascular care, as expertise and advanced technologies were unevenly distributed across the country's autonomous regions. Given that CVD is the leading cause of mortality, ensuring consistent, high-quality treatment required concentrating resources and experience in a limited number of centres.

**Strategy:** By means of a Royal Decree, Spain established Centres of Excellence for highly specialised care, including cardiovascular medicine such as the Centro Nacional de Investigaciones Cardiovasculares (CNIC). These centres were accredited based on strict criteria of expertise, case volume, technology, multidisciplinary teams, and reporting capacity. To guarantee equal access, the Healthcare Cohesion Fund financed patient referrals across regions, allowing all citizens, including those in island territories, to receive care in the designated benchmark centres. Accreditation was subject to regular review to ensure ongoing quality and accountability.

**Impact:** The centres strengthened Spain's ability to provide equitable, high-quality cardiovascular care. By concentrating expertise and resources, it aims to enhance outcomes, decrease care variability, and increase efficiency in the use of advanced technologies. These centres now serve not only as treatment hubs but also as national references for training, clinical guidance, and innovation in cardiovascular medicine.

# Policy Proposal 3: Establish a Cardiovascular Health Knowledge Centre to support real-time decision-making

#### Predictive Monitoring for Cardiac Device Patients xvii

**Situation:** In Trento, Italy, traditional in-office follow-up for patients with implantable cardiac devices was resource-intensive and insufficiently predictive of hospitalisation risks.

**Strategy:** A remote monitoring programme for 402 patients using implantable devices such as implantable cardioverter-defibrillators (ICDs) and Cardiac Resynchronisation Therapy Devices (CRT-Ds) was implemented, supported by a cost-comparison exercise.

**Impact:** Hospitalisation for cardiovascular health-related matters dropped from 51% to 25% with per-patient savings of EUR 4.831 for payers and EUR 7.005 for hospitals over a period of two years. The results showcase the potential for a Cardiovascular Health Knowledge Centre to guide EU-wide digital monitoring protocols.

### Informing evidence-based public health decision-making to tackle valvular heart disease inequalities in Italy

**Situation:** Valvular heart disease (VHD) is the third leading cause of cardiovascular morbidity, with its incidence and public health impact projected to increase significantly. Still, detailed understanding of prevalence and burden of heart valve disease often lacks, leading to lack of evidence to ensure evidence-based decision-making that could tackle inequalities in access to detection and care.

**Strategy:** a prospective registry of valve disease in asymptomatic Italian elderly populations (PREVASC), designed to assess the prevalence of heart valve disease among elderly, asymptomatic individuals (i.e. considering themselves healthy) in rural areas across Italy, characterised by a less medicalised environment. The study was endorsed by participating public municipalities. Elderly citizens were recruited on a voluntary basis, utilising public health billboards.

**Impact:** Over 1100 elderly citizens participated. In 94% of individuals aged 75 years and above, at least one valvular defect was detected, with 22,5% presenting moderate or severe disease.

### Policy Proposal 4: Accelerate Cardiovascular Health Innovation Access Pathways from Early Evidence up to procurement and Funding/Reimbursement

#### Predictive heart failure monitoringxix helps reduce hospitalisations

**Situation:** Heart failure patients require personalised monitoring, yet innovations in digital health often face fragmented regulatory and funding pathways.

**Strategy**: The algorithm embedded in implantable defibrillators was trialled in Belgium and the Netherlands to predict decompensated heart failure events.

**Impact:** Hospitalisations were reduced from 27 to 7 per year, while average hospital stays dropped from 16 to 7 days. The economic valuation confirmed a reduction in total care costs, underscoring the need for faster innovation access through EU procurement mechanisms.

#### Al-guided Hemodynamicsxx helps reduce severe acute kidney injury

**Situation:** Variability in hemodynamic management during cardiac surgeries contribute to complications such as acute kidney injury (AKI) and extended ICU stays.

**Strategy:** A multi-hospital study introduced artificial intelligence (AI)-guided Hypotension Prediction Index (HPI) management within enhanced recovery pathways.

**Impact:** While overall AKI rates remained steady, severe AKI dropped by 40%, while intensive care unit stays were reduced by 6.8 hours, and ventilation time dropped by 4.4 hours. The findings highlighted the added value of Aldriven solutions and the urgency of integrating such technologies through streamlined EU-wide assessment and funding pathways.

### Cost-Effective Remote Patient Monitoring for Heart Failure in European Countries\*xi

**Situation:** Heart failure (HF) remains a major cause of mortality and hospitalisation across Europe, driving high healthcare costs. Traditional reactive care models often miss early signs of deterioration, leading to avoidable admissions and poorer outcomes. There is growing interest in digital tools to enable more proactive and continuous management.

**Strategy:** This study assessed the cost-effectiveness of non-invasive remote patient monitoring (RPM) in the Netherlands, UK, and Germany using a lifetime Markov model. RPM enables early detection of HF deterioration at home, reducing hospitalisation risk. The model included both healthcare and societal costs, such as informal care and non-medical consumption during life years gained.

**Impact:** RPM—using non-invasive digital tools to monitor heart failure patients at home—enabled early detection of deterioration, reducing costly hospitalisations and improving quality of life. While lifetime costs increased due to longer survival and related non-medical needs, RPM remained cost-effective in all three countries. From a healthcare perspective, the cost per QALY gained ranged from €11,432 to €12,977, confirming that digital, home-based monitoring supports proactive, value-driven heart failure care.

### Improving patient outcomes and reducing healthcare burden for patients with heart valve disease thanks to value-based procurement in Spain<sup>xxii</sup>

Situation: Aortic Stenosis (AS) is becoming more common due to an ageing population, while awareness among both the public and healthcare professionals (HCPs) is low. Existing healthcare pathways are inefficient, delaying patient detection, referral, and treatment. This project aimed to create a new, integrated pathway to improve patient outcomes and alleviate the burden on hospitals and HCPs.

**Strategy:** The Hospital Clíníc Barcelona Cardiovascular Institute implemented the MITMEVA programme, a comprehensive and multidisciplinary initiative to provide effective and personalised care for AS patients. Co-funded by the EU, the programme aimed to improve the quality and efficiency of clinical management for all AS patients, regardless of whether they required surgical or percutaneous means (TAVI) or medical treatment. The strategy involved a thorough analysis of bottlenecks and unmet needs across the entire care pathway, from primary care to hospital discharge, in addition to the integration of innovative technologies and solutions.

**Impact:** The MITMEVA programme used 11 key performance indicators (KPIs) to improve the AS care pathway, including public awareness campaigns, a single-entry referral system, and risk-sharing agreements, leading to significant results. Quality-adjusted-life-years increased by 1.78 while hospital complications reduced by 19,7%. This was accompanied by a reduction in treatment times, as referral times dropped by 24,7%, while the average length of hospital stays reduced by 4 days. The programme also led to a 46% increase in early detection and diagnosis due to targeted training for HCPs and public awareness campaigns. Overall, the programme significantly improved clinical and economic outcomes, proving the value of organisational innovations in healthcare.

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