EUROPEAN PATIENT SAFETY FOUNDATION

Tackling Cardiovascular Disease Across Europe

Placing Patient Safety at the Heart of Europe's Upcoming Cardiovascular Health Plan
Contribution of the European Patient Safety Foundation

Introduction

Cardiovascular diseases (CVD) remain the leading cause of death and disability in Europe, responsible for an estimated 1.7 million deaths each year[1] and placing a significant and growing burden on individuals, families, and health systems.

As populations age and treatments become increasingly complex, the impact of CVD extends well beyond clinical outcomes to include profound social and economic consequences for all Member States. It drives rising healthcare costs through hospitalisations and long-term care. It also reduces participation in the general workforce, as many people living with CVD or caring for affected family members, are unable to work or must reduce their hours. At the same time, health services face growing demands that strain the medical workforce, leading to shortages and service disruptions.

Together, these pressures threaten the sustainability of health systems across all Member States.

The upcoming EU Cardiovascular Health Plan represents a historic opportunity to change this trajectory. To succeed, the Plan must go beyond improving access to prevention and treatment. It must also ensure that care is safe, reliable, and centred on people's needs.

Cardiovascular care involves highly complex pathways with frequent transitions between care settings and intensive use of high-risk interventions such as invasive procedures and powerful medications. These realities create inherent risks. If these risks are not systematically addressed, they can lead to avoidable harm that undermines trust, worsens outcomes, and, again, threatens the sustainability of healthcare systems.

Patient safety is therefore not an optional add-on to cardiovascular health, it is its foundation. A system that tolerates avoidable harm cannot deliver high-quality and cost-effective care. By placing safety at the heart of the Plan, Europe can ensure that investments in prevention, innovation, and medical workforce development translate into real-world improvements for patients and professionals.

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[1] OECD/European Commission (2024), *Health at a Glance: Europe 2024: State of Health in the EU Cycle*, OECD Publishing, Paris, https://doi.org/10.1787/b3704e14-en.

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This approach is also closely aligned with the EU's broader health policy agenda, which calls for resilient, sustainable, and people-centred healthcare systems capable of withstanding demographic, financial, and workforce pressures.

The challenge of systemic sustainability of the healthcare systems is particularly urgent. Workforce shortages, financial constraints, and growing demand are converging to create a fragile environment where even small failures can cascade into major disruptions. In this context, unsafe care has a double impact: it directly harms patients and simultaneously wastes resources, exacerbating the very pressures health systems are struggling to manage.

Addressing safety is therefore a strategic necessity for ensuring the success of a cardiovascular care plan at the European scale. By taking a safety-first approach, Europe can reduce harm, build trust, and create a sustainable foundation for cardiovascular health that benefits both patients and healthcare professionals.

This document develops why patient safety must be at the core of the EU Cardiovascular Health Plan and provides practical recommendations for achieving this goal.

WHO WE ARE?

The European Patient Safety Foundation (EUPSF) was established in 2013 and has been actively engaged across Europe since 2019. As a multi-stakeholder network, we bring together leading hospitals, patient organisations, national patient safety and quality of care platforms, insurers, scientific societies, and industry partners. Our mission is to reduce avoidable harm and improve the quality of care through collaboration, knowledge exchange, and innovation. Over recent years, we have expanded our network to include leading experts and organisations from across Europe, creating a platform for shared learning and joint action on safety.

Through initiatives such as the Fighting Fatigue Together campaign, which addresses healthcare workforce well-being, continuous exchanges with the leading patient safety stakeholders, and our work on the safe integration of digital innovation, we demonstrate how collective action can generate practical solutions to systemic safety challenges. These experiences inform the recommendations we present in this contribution.

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1. Why patient safety must be at the heart of the EU Cardiovascular Health Plan

1.1 Ethical Imperative: No one should be harmed in healthcare

Every year, millions of Europeans experience harm while receiving healthcare. The scale of the problem has been documented in numerous international reports.

According to OECD's work on patient safety[2],[3], 1 in 10 patients experience harm during hospital care, while 4 in 10 patients are harmed in primary or ambulatory care settings across OECD countries.

These figures represent not just statistics but real people whose lives are impacted by events that could often have been prevented.

Cardiovascular care is particularly high-risk because of its technical complexity, the frequent use of powerful medications and invasive procedures, and the vulnerability of the patient population. When harm occurs in this context, the consequences are often severe, including long-term disability, loss of independence, or death.

The WHO Global Patient Safety Action Plan 2021-2030, formally adopted on 28 May 2021 by the 74th World Health Assembly frames patient safety as a global public health priority with a vision of "a world in which no one is harmed in healthcare, and every patient receives safe and respectful care, every time, everywhere."

Preventing avoidable harm is therefore an ethical imperative. Citizens across Europe rightly expect that when they seek care, they will be helped, not harmed. Every instance of preventable harm represents a breach of trust between healthcare systems and the people they serve. This trust is foundational: without it, even the most advanced treatments and technologies lose their legitimacy.

For cardiovascular care, where patients often face life-threatening conditions and rely on timely, precise interventions, the ethical duty to ensure safe care is even more pressing. Safety must be embedded at every level, from bedside practices to national policy decisions.

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[2] Slawomirski, L. and N. Klazinga (2022), "The economics of patient safety: From analysis to action", *OECD Health Working Papers*, No. 145, OECD Publishing, Paris, https://doi.org/10.1787/761f2da8-en.
[3] Auraaen, A., L. Slawomirski and N. Klazinga (2018), "The economics of patient safety in primary and ambulatory care: Flying blind", *OECD Health Working Papers*, No. 106, OECD Publishing, Paris, https://doi.org/10.1787/baf425ad-en.

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1.2 Economic Imperative: The cost of unsafe care

Unsafe care is not only unethical but also economically unsustainable.

Approximately 15% of hospital expenditure[4] is attributed to treating patient safety failures in rich countries. The OECD also estimates that more than USD 54 billion per year (about 11% of total pharmaceutical spending in OECD countries) is consumed by costs associated with medication-related hospital admissions and extended inpatient stays due to preventable harms[5].

These numbers underscore a fundamental point: unsafe care wastes resources at a time when health systems face mounting financial pressures.

In cardiovascular care, these costs are even higher due to several factors. First, the high prevalence of cardiovascular diseases, which affect millions of Europeans, places a constant and significant demand on health services. Second, treatment is often long-term and complex, requiring the management of complex medication regimens and frequent hospitalisations. Finally, cardiovascular care relies heavily on advanced technologies and specialised staff, both of which are costly to deploy and maintain. Together, these elements compound the financial and operational pressures on healthcare systems, making the safe and efficient delivery of care even more critical.

Unsafe care also has a direct impact on the healthcare workforce. When harm occurs, it affects not only the patient but also the professionals involved. This is known as the Second Victim Phenomenon, first described by Dr. Albert Wu and later studied extensively in Europe (see section 3).

Second victims experience intense psychological distress (guilt, anxiety, and even post-traumatic stress) following adverse events. If left unaddressed, it can have serious consequences for both healthcare professionals and patients. It may lead to burnout, which reduces the quality and consistency of care, as well as absenteeism that creates gaps in service delivery. In some cases, professionals leave the healthcare workforce altogether, worsening existing shortages. Others may adopt defensive medical practices, focusing more on avoiding blame than on improving patient outcomes.

The consequences are twofold: on a human level, healthcare professionals suffer in silence, and their capacity to deliver safe and compassionate care is diminished; on an

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[4] Slawomirski, L., A. Auraaen and N. Klazinga (2017), "The economics of patient safety : Strengthening a value-based approach to reducing patient harm at national level", *OECD Health Working Papers*, No. 96, OECD Publishing, Paris, https://doi.org/10.1787/5a9858cd-en.
[5] de Bienassis, K. et al. (2022), "The economics of medication safety: Improving medication safety through collective, real-time learning", *OECD Health Working Papers*, No. 147, OECD Publishing, Paris, https://doi.org/10.1787/9a933261-en.

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economic level, health systems face rising expenses related to recruitment and training, as well as the indirect costs linked to litigation and inefficiency[6].

By reducing harm, the EU Cardiovascular Health Plan can help stabilise and strengthen the workforce, protecting both patients and professionals while reducing financial strain on Member States.

1.3 Safety as the foundation of quality and value

Over the past decade, many European health systems have started to adopt value-based care models, which focus on achieving the best possible health outcomes relative to the resources invested. This shift reflects a growing consensus: health systems must not only provide care but do so efficiently and equitably.

Patient safety is the starting point for value-based care. Unsafe care generates complications, delays, and readmissions that directly undermine quality, while safety improvements create the stable foundation needed for consistent and reliable processes and outcomes. Without safety, neither efficiency nor value can be achieved, as unsafe care inherently wastes resources and erodes public trust.

The European Beating Cancer Plan[7], launched in 2021, provides a clear precedent. It mobilised EU-level funding, coordinated action, and stakeholder engagement to drive progress in cancer prevention, diagnosis, and treatment. By embedding safety as a core principle, it also demonstrated how targeted, coordinated strategies can transform care across a disease area.

A similar, safety-centred approach is now needed for cardiovascular health. By treating safety as the foundation rather than an afterthought, the EU can ensure that investments in prevention, innovation, and workforce development deliver meaningful, measurable improvements.

2. Building on EU and global commitments

Europe already has a strong legacy of patient safety leadership, but progress has been uneven. While significant steps have been taken to improve safety and reduce harm, many initiatives have stalled or lacked the necessary mechanisms for implementation and accountability. The EU Cardiovascular Health Plan now provides a unique opportunity to

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[6] The costs linked to the second victim are developed under section 3.2.
[7] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Europe's Beating Cancer Plan - COM/2021/44 final

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renew and expand this leadership, ensuring that cardiovascular care is guided by a clear, coordinated strategy.

2.1 EU milestones and achievements

The foundation of EU action on patient safety was laid with the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare-associated infections (2009/C 151/01).

This landmark document urged all Member States to develop comprehensive national policies and programmes on patient safety, establish reporting and learning systems to identify, analyse, and prevent adverse events, foster patient empowerment by providing accessible information on safety practices, promote training and education for healthcare workers, and encourage cooperation with industry partners to design safer products, medicines, and technologies.

This Recommendation was a turning point in recognising patient safety as a shared European concern. It created a common language for safety and stimulated cross-border collaboration. However, its non-binding nature meant that implementation depended entirely on the political will and resources of each Member State. Progress was therefore uneven, with some countries advancing rapidly and others lagging behind.

Following 2009, patient safety was integrated into several EU health programmes and initiatives, including the early funding streams for safety research and quality improvement.

However, by 2016, momentum began to fade. Dedicated EU funding for patient safety decreased significantly, and no successor mechanism was put in place to maintain consistent support. As a result, fragmentation increased, leaving patients across Europe with highly variable levels of protection and reporting infrastructure.

Recent policy developments have provided opportunities to bring safety back onto the agenda. The European Health Union framework, developed in response to the COVID-19 pandemic, emphasises resilience and preparedness across Member States. Similarly, the EU4Health Programme has made substantial investments in strengthening health systems and addressing cross-border health threats. Yet, while these initiatives have focused on pandemic response, digital health, and cancer control, dedicated funding and political attention to patient safety remain limited. This gap risks leaving systemic safety issues unaddressed, particularly in high-risk domains such as cardiovascular care.

One promising development is the proposed European Health Data Space (EHDS), which aims to enable secure cross-border data sharing, e-prescribing, and e-dispensing. By doing so, the EHDS has the potential to improve continuity of care for patients moving between healthcare settings or Member States, support the development of digital decision-support tools for clinicians, and enhance medication safety by reducing duplication and errors.

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However, these benefits will only be realised if robust safety governance is ensured throughout the implementation of the EHDS. Without this, new digital infrastructures could inadvertently introduce new sources of risk, such as data fragmentation, interoperability failures, or cybersecurity threats.

2.2 Global frameworks and leadership

European action on patient safety must also align with global frameworks, ensuring that national and regional strategies are consistent with international best practices.

The most comprehensive global roadmap is provided by the WHO Global Patient Safety Action Plan 2021–2030 entitled "Towards eliminating avoidable harm in healthcare", adopted by all WHO Member States in 2021[8], which sets out seven key strategic objectives, including:

- Building high-reliability health systems and organisations that minimise risk.
- Establishing strong reporting and learning mechanisms to drive continuous improvement.
- Supporting workforce education and well-being, recognising that safe care depends on a healthy, well-trained workforce.
- Prioritising medication safety.
- Strengthening infection prevention and control to reduce healthcare-associated infections[9] and antimicrobial resistance.

These priorities were reaffirmed through the adoption of the Montreux Charter on Patient Safety ("Less Harm, Better Care – From Resolution to Implementation") launched at the 5th Global Ministerial Summit on Patient Safety in Montreux, Switzerland, on 23–24 February 2023.

The Montreux Charter calls for:

- Integration of safety into every health policy decision, at all levels of governance.
- Recognition of patient safety as essential for health system sustainability, especially in the face of workforce shortages and financial pressures.
- Enhanced collaboration across sectors and borders, ensuring that lessons learned in one country benefit all.
- Engagement of patients and families as partners in safety strategies.

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[8] This global action plan was adopted by Seventy-Fourth World Health Assembly in 2021 - ISBN: 978-92-4-003270-5

[9] Healthcare-associated infections remain a persistent challenge in cardiovascular care, with European studies showing infection rates of 17–24% among acute heart failure patients in intensive care units. These figures illustrate why infection prevention remains a key priority within global safety frameworks.

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Both the WHO Action Plan and the Montreux Charter underscore that patient safety is inseparable from broader health policy goals such as equity, sustainability, and trust. They provide a clear framework for Europe to align its actions with the global movement towards zero avoidable harm.

2.3 Strengthening governance and accountability

Despite strong frameworks such as the WHO Global Patient Safety Action Plan and the Montreux Charter, patient safety in Europe remains fragmented and inconsistent. Some Member States have developed advanced national strategies, reporting systems, and education programmes, while others lack even the basic structures needed to systematically monitor and reduce harm. This results in wide disparities between countries and prevents collective progress.

One key gap is the absence of a formal governance mechanism at national and EU level. To date, there has been no coordinated requirement for Member States to designate competent authorities or bodies responsible for patient safety, equipped with the mandate and resources to lead safety policies. Moreover, there is often no structured way to engage patient organisations, scientific societies, professional associations, and researchers in a shared, multi-stakeholder approach to policy design and implementation.

Establishing such governance structures would create clear lines of accountability and ensure that patient safety is not treated as a secondary or optional issue. These national authorities could also form a European network, fostering collaboration, data sharing, and rapid dissemination of lessons learned across borders. This would strengthen both national and EU capacity to reduce harm and would provide the institutional foundation needed for sustained improvement, particularly in high-risk areas such as cardiovascular care.

2.4 Practical recommendations

The EU Cardiovascular Health Plan represents a significant opportunity to close persistent gaps and reaffirm Europe's leadership in patient safety. To make this vision a reality, the Plan must be anchored in clear goals and supported by the structures and resources needed for implementation.

To achieve this, the Plan should:

- **Set clear, measurable safety goals for cardiovascular care**, aligned with the WHO Global Patient Safety Action Plan and the Montreux Charter, to reduce harm and improve outcomes across the entire cardiovascular pathway.
- **Require Member States to designate competent national authorities or platforms for patient safety, supported by secure EU and national funding**. These structures should adopt a multi-stakeholder approach and prioritise cardiovascular care as a first focus area, reflecting the burden and complexity of CVD, while creating a model that can later be extended to other domains of care.

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- **Promote harmonisation and standardisation of safety practices specifically for cardiovascular services**, ensuring equitable levels of protection and quality for patients across Europe.
- **Create mechanisms for cross-border learning and rapid sharing of innovations**, including the possible development of a European network of Centres of Excellence. These centres should primarily focus on improving safety and quality of cardiovascular care, serving as hubs to test, validate, and scale best practices. By connecting research, innovation, and clinical practice, they can help reduce inequalities, strengthen workforce expertise, and ensure that new approaches are implemented safely and effectively across Member States.
- **Strengthen patient safety within the implementation of related EU initiatives**, such as the European Health Data Space and EU4Health, ensuring they directly support safe and effective digital tools, data sharing, and workforce development for cardiovascular care.

By combining clear objectives with strong governance and sustainable financing, the EU can build a coherent and effective framework for safe, equitable, and resilient cardiovascular care, one that protects patients and healthcare professionals while strengthening the performance of health systems across Europe.

3. Addressing workforce fatigue and well-being: A systemic risk

3.1 Introduction: Workforce fatigue as a core safety challenge

Cardiovascular care depends on highly skilled and specialised teams, including cardiologists, cardiac surgeons, nurses, technicians, and support staff. These professionals work under intense time pressure and in complex, high-stakes environments. Every decision and every action must be precise, as errors can have immediate and life-threatening consequences.

Across Europe, however, fatigue and burnout among healthcare professionals have reached alarming levels. A 2024 joint survey[10] by the European Board of Anaesthesiology (EBA) and the National Anaesthesiology Societies Committee (NASC) of the European Society of Anaesthesiology and Intensive Care (ESAIC), covering 42 countries, found that over 90% of anaesthesiologists reported experiencing fatigue related to their work. The study underscores fatigue as a widespread systemic problem in European healthcare, with significant implications for both patient safety and clinician well-being.

The Health Services Safety Investigations Body (HSSIB), in its report ‘Fatigue risk in

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[10] Camilleri Podesta, Anne Marie; Redfern, Nancy; Abramovich, Igor; Mellin-Olsen, Jannicke; Oremuš, Krešimir; Kouki, Pinelopi; Guasch, Emilia; Novak-Jankovic, Vesna; Sabelnikovs, Olegs; Bilotta, Federico; Grigoras, Ioana. Fatigue among anaesthesiologists in Europe: Findings from a joint EBA/NASC survey. European Journal of Anaesthesiology 41(1):p 24-33, January 2024. | DOI: 10.1097/EJA.0000000000001923

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healthcare and its impact on patient safety' in April 2025[11], introduced the concept of fatigue and outlined the risk posed to patient safety from staff fatigue. This investigation which engaged with a wide range of healthcare staff in United Kingdom to learn what impact fatigue had on patient safety in acute NHS hospitals, adopted the International Civil Aviation Organization's definition of fatigue as "*a physiological state of reduced mental or physical performance capability resulting from sleep loss, extended wakefulness, circadian phase [the natural daily internal body clock], and/or workload (mental and/or physical activity) that can impair a person's alertness and ability to perform safety related operational duties*."

The problematic of fatigue applies also to the healthcare professionals working in cardiac services. During the COVID-19 pandemic, a survey[12] of the European Society of Cardiac Imaging covering 34 countries revealed the vulnerability of this workforce: two-thirds of the imaging specialists reported worsening signs of burnout, 44% had considered leaving their job, and more than half lacked access to formal mental-health support. While these figures reflect a period of exceptional strain, they underscore how quickly already fragile systems can become overwhelmed.

Beyond the pandemic, the problem persists. A multicentre study[13] of over 400 cardiac nurses from polish cardiology hospitals found high emotional exhaustion in 53% and high depersonalisation in 52.5%, pointing to chronic and systemic pressures. Similarly, a national survey[14] of Dutch cardiologists identified substantial work exhaustion linked to heavy workload and poor work-life balance, factors that remain relevant today. These findings demonstrate that fatigue is not only widespread but also deeply systemic, affecting every layer of cardiovascular care.

Workforce shortages, increasing demand, and administrative burdens combine to create a situation where many teams are pushed beyond sustainable limits. Fatigue is too often framed as an individual problem, with solutions focused on personal resilience or coping

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[11] HSSIB Investigation report: The impact of staff fatigue on patient safety (24 April 2025)

[12] Joshi SS, Stankovic I, Demirkiran A, Haugaa K, Maurovich-Horvat P, Popescu BA, Cosyns B, Edvardsen T, Petersen SE, Carvalho RF, Cameli M, Dweck MR. EACVI survey on burnout amongst cardiac imaging specialists during the 2019 coronavirus disease pandemic. Eur Heart J Cardiovasc Imaging. 2022 Mar 22;23(4):441-446. doi: 10.1093/ehjci/jeac002. PMID: 35061874; PMCID: PMC8807202.

[13] Larysz A, Prokopowicz A, Zakliczyński M, Uchmanowicz I. Occurrence of Professional Burnout and Severity of Depressive Symptoms among Cardiac Nurses: A Cross-Sectional Study. Int J Environ Res Public Health. 2021 Nov 16;18(22):12038. doi: 10.3390/ijerph182212038. PMID: 34831790; PMCID: PMC8624845.

[14] Bogerd, R., Tijssen, J. G. P., van der Linde, D., & Kemps, H. M. C. (2023). Work-Related Well-Being Among Dutch Cardiologists – A National Survey. European Journal of Preventive Cardiology. DOI: 10.1093/eurjpc/zwad197.

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strategies. In reality, fatigue is a systemic issue that undermines both patient safety and the sustainability of health systems.

When professionals are exhausted, their ability to concentrate, communicate, and make sound decisions diminishes[15][16]. This increases the likelihood of mistakes, delays, and miscommunication, each of which can directly endanger patients. In cardiovascular care, where interventions are complex and time-sensitive, even a minor lapse can escalate into severe harm. Addressing workforce fatigue is therefore not an optional support measure but a core patient safety strategy and a prerequisite for continuity of care.

3.2 The vicious cycle of fatigue and harm

The resources collected through our European collaborative and award-winning Fighting Fatigue Together (FFT) campaign[17] highlights the self-reinforcing cycle that links fatigue to harm and workforce shortages.

Fatigue diminishes vigilance, decision-making, and communication. As performance deteriorates, errors become more likely[18], from medication mistakes to procedural complications.

When harm occurs, it affects not only patients but also the professionals involved, who can experiment Second Victim Phenomenon, as already explained in section 1.2. Healthcare professionals involved in adverse events often experience profound psychological distress, including guilt, shame, anxiety, and symptoms of post-traumatic stress. A recent study[19] indicates that among nurses in Germany, approximately 59% in have experienced the second victim phenomenon at least once in their career.

Without timely and effective support, many of these professionals either leave the workforce entirely[20] or change their behaviour in ways that undermine safety. Some adopt defensive medical practices, avoiding complex cases or working cautiously to prevent blame rather than focusing on optimal care. Others withdraw emotionally, reducing their engagement with patients and teams. These responses deepen the crisis: as more staff

[15] FATIGUE IN ANAESTHESIOLOGY – CALL FOR A CHANGE OF CULTURE AND REGULATIONS, Nancy Redfern, Federico Bilotta, Igor Abramovich, Ioana Grigoras, in European Journal of Anaesthesiology 40(2):p 78-81, February 2023.
[16] The Helsinki Declaration on Patient Safety in Anaesthesiology 2.0. - https://helsinkipatientsafety.org/
[17] Fighting Fatigue Together campaign Resources https://www.fightingfatiguetogether.eu/resources
[18] Physician burnout undermines safe healthcare, Matthias Weigl, BMJ 2023, 378
[19] Strametz, R.; Fendel, J.C.; Koch, P.; Roesner, H.; Zilezinski, M.; Bushuven, S.; Raspe, M. Prevalence of Second Victims, Risk Factors, and Support Strategies among German Nurses (SeViD-II Survey). *Int. J. Environ. Res. Public Health* 2021, *18*, 10594. https://doi.org/10.3390/ijerph182010594
[20] ASSOCIATIONS OF PHYSICIAN BURNOUT WITH CAREER ENGAGEMENT AND QUALITY OF PATIENT CARE: SYSTEMATIC REVIEW AND META-ANALYSIS, Alexander Hodkinson, et. all, BMJ 2022;378:e070442 | doi: 10.1136/bmj-2022-070442

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leave, the workload for those who remain increases, leading to even higher levels of fatigue and stress.

This dynamic creates a destructive spiral: Fatigue leads to errors → errors lead to trauma → trauma leads to workforce attrition → attrition leads to increased workload → increased workload leads to more fatigue.

This cycle transcends borders and healthcare systems. In the United Kingdom, for example, a comprehensive study[21] found 40 clear correlations between staffing levels and patient safety indicators, demonstrating that inadequate staffing is directly associated with increased harm. Similar findings have been reported in other Member States, reinforcing the link between workforce well-being and patient outcomes.

Beyond the human cost, this cycle has significant economic consequences. The departure of skilled staff increases recruitment and training expenses, while absenteeism disrupts care delivery. According to a 2025 German modelling study[22], the replacement costs for healthcare professionals leaving the workforce due to second victim trauma are estimated at €150,000 per physician and €50,000 per nurse, illustrating the substantial financial burden that turnover imposes on health systems.

Defensive medical practices and litigation add further costs, diverting resources away from patient care and innovation. Unsafe care thus creates a dual burden: it harms patients and simultaneously wastes precious healthcare resources.

3.3 Why cardiovascular care is especially vulnerable

The impact of fatigue and workforce shortages is particularly acute in cardiovascular care. This field involves some of the most complex, high-risk interventions in modern medicine. Emergencies such as heart attacks or arrhythmias require immediate, coordinated responses. Fatigue slows reaction times and clouds judgment, reducing the effectiveness of life-saving interventions.

Cardiovascular patients also frequently require multiple medications, often with narrow therapeutic windows. Managing these regimens safely demands constant attention and precise communication between hospital teams, primary care providers, and families.

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[21] Leary, A., Cook, R., Jones, S., Mellor, P., Owen, R., Richardson, A., … & Wade, C. (2016). Mining routinely collected acute data to reveal non-linear relationships between nurse staffing levels and outcomes. BMJ Open, 6(12), e011177. https://doi.org/10.1136/bmjopen-2016-011177

[22] Strametz, R., Roesner, H., Neusius, T., Mira, J. J., et al. (2025). The Economic Implications of Psychosocial Peer Support for Health Workers in German Hospitals. Journal of Healthcare Leadership, 17, 15–22. https://doi.org/10.2147/JHL.S498789

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Fatigue increases the risk of prescribing errors, incorrect dosing, or missed contraindications, especially during transitions of care, such as discharge from hospital to home. These transition points are consistently identified as high-risk moments for avoidable harm.

Moreover, shortages of specialised professionals, including cardiologists, cardiac nurses, perfusionists, and technicians, compound the problem. When these roles are understaffed, each remaining professional must take on a heavier workload. This accelerates fatigue, creating a feedback loop where systemic pressures grow more intense over time.

Addressing workforce fatigue in cardiovascular care is therefore not a secondary concern but a strategic necessity. Without decisive action, both patient outcomes and the overall resilience of health systems will continue to deteriorate.

3.4 Practical recommendations

To break the cycle of fatigue and harm, coordinated measures are needed at both Member State and EU levels. The EU Cardiovascular Health Plan can play a pivotal role by setting standards, providing resources, and fostering collaboration across borders. Based on the findings of the FFT campaign, the recommendations of the RESCUE project, and international best practices, we recommend the following actions:

- **Promote safe staffing and workload monitoring**: Encourage Member States to adopt evidence-based minimum staffing ratios for cardiovascular care, supported by EU-level benchmarking and funding for workforce planning tools.
- **Support fatigue-mitigating scheduling**: Issue guidance on best practice for shift design and provide funding to pilot innovative scheduling models
- **Promote fatigue risk management strategies through EU guidance and shared learning:** Encourage Member States and healthcare organisations to develop and implement fatigue risk management strategies by providing EU-level guidance, tools, and platforms for sharing best practices. This could include education resources on recognising and mitigating fatigue, examples of rest facility standards, and promoting a fatigue-aware organisational culture.
- **Integrate workforce well-being into EU patient safety policies and funding programmes**: Recognise staff fatigue as a critical patient safety risk by incorporating it into EU-level health policy priorities and funding mechanisms, such as EU4Health and COST. This includes supporting research, cross-border projects, and pilot programmes to monitor and mitigate fatigue, while fostering collaboration between Member States to develop harmonised approaches.

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- **Develop EU guidance on second victim support and peer networks based on the recommendations of the RESCUE initiative**[23]: Create a European framework defining core principles for peer-to-peer support programmes and fund pilot projects to test scalable models, leaving actual implementation to Member States and hospitals.
- **Integrate fatigue into EU patient safety and risk management frameworks**: Recognise fatigue as a critical patient safety risk by including it in EU health policy guidance and exploring regulatory pathways to require hospitals to monitor and mitigate fatigue systematically.
- **Create EU-level knowledge-sharing and coordination mechanisms**: Through EU4Health and other programmes, support cross-border learning and data collection on fatigue-related risks and interventions.

By acting on these recommendations, the EU can stabilise the cardiovascular workforce, reduce avoidable harm, and build a foundation for sustainable, high-quality care. Failing to address fatigue would allow the destructive cycle of harm and attrition to continue, with consequences for both patients, healthcare professionals and health systems that Europe cannot afford to ignore.

4. A new vision of safety for digital innovation and AI

4.1 The two sides of digital innovation

Digital technologies are reshaping cardiovascular care. Advanced tools, including Artificial Intelligence (AI), remote monitoring systems, connected devices, and minimally invasive technologies, offer unprecedented possibilities for early detection, clinical decision support, treatment optimisation, and patient follow-up. These innovations can improve outcomes, personalise care, and increase efficiency across the entire cardiovascular pathway.

However, these opportunities may come with new forms of risk. Unlike traditional devices, many digital technologies are adaptive, dynamic, and deeply integrated into daily care processes. Errors or biases in algorithms, unclear responsibilities, or poor integration into workflows can lead to unintended harm. These risks are systemic, emerging from the interaction between people, technology, and organisations rather than from technical flaws alone.

The EU already has a strong regulatory foundation, including the Medical Device Regulation (MDR), the AI Act, and the Health Technology Assessment (HTA) Regulation. These

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[23] A European Strategy for Supporting Second Victims in Healthcare and Long-Term Care. RESCUE Initiative, COST Action CA19113; 2025.

frameworks play a vital role in ensuring safety while enabling innovation to reach the market. However, they must continuously evolve to keep pace with rapid technological advances.

The challenge is to strike the right balance between efficiency and safety: ensuring timely market access for innovations that benefit patients, while maintaining robust safeguards to protect them from harm. Achieving this balance requires a collaborative approach where innovators, healthcare systems, and regulators work together to generate real-world evidence, identify emerging risks, and ensure that regulatory pathways remain clear and predictable.

4.2 Moving beyond compliance: a systemic approach to safe integration

For decades, patient safety strategies have relied mainly on reactive approaches, such as incident reporting and root-cause analysis. These remain essential, but they focus on understanding harm after it has occurred.

The digital transformation of healthcare opens up new possibilities. With real-time data, connected systems, and advanced analytics, risks can now be anticipated and prevented rather than only investigated afterwards. This enables health systems to move from reacting to adverse events to proactively detecting early warning signs, addressing recurring inefficiencies, and continuously improving quality and safety.

This broader perspective underpins four interconnected pillars for safely integrating innovation into cardiovascular care:

The first pillar: Human–technology collaboration and trust

Digital tools must support, not replace, the expertise of healthcare professionals. Clinicians need to understand how these systems work, their limitations, and how to integrate them into decision-making. Training should include not only technical skills but also ethical, legal, and professional considerations. Simulation-based education can help teams prepare for complex scenarios involving human–technology interactions, fostering mutual trust and confidence.

The second pillar: Organisational readiness and interoperability
Introducing new technologies is an organisational transformation, not just a technical upgrade. Poorly embedded systems can create cognitive overload, alarm fatigue, or unsafe workarounds. Successful integration requires seamless workflows and strong EU-wide standards for interoperability, usability, and cybersecurity, ensuring that technologies work reliably across diverse healthcare settings.

The third pillar: Ethical and legal accountability
As technologies increasingly influence care decisions, there must be clarity about roles and responsibilities when harm occurs. Hospitals and professionals need practical guidance on

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applying evolving regulations, such as the revised Product Liability Directive and the forthcoming AI Act, in day-to-day practice. Transparent reporting and clear governance mechanisms are vital to maintain public and professional trust.

The fourth pillar: Collaborative co-design and workforce well-being
Safe adoption depends on involving frontline professionals and patients early in the design and implementation of innovations. When end-users help shape the tools they will use, these technologies are more likely to simplify care, reduce stress, prevent the introduction of new sources of fatigue or error, and increase the level of satisfaction of the health professionals about their own work.

4.3 Why this matters for cardiovascular care

Cardiovascular care is among the most complex areas of healthcare. It involves frequent transitions between settings, reliance on highly specialised teams, and intensive use of data to guide decisions. These characteristics make it particularly well-suited for innovation but also highly vulnerable if innovations are poorly integrated.

Examples include early detection of acute events, remote patient follow-up after cardiac surgery, digital medication management systems, and advanced therapeutic devices. Each of these technologies can dramatically improve outcomes and reduce harm but without careful planning, they can also create delays, misinterpretations, or entirely new safety risks.

The EU Cardiovascular Health Plan must therefore focus on creating the right conditions for safe digital adoption, ensuring that innovation strengthens cardiovascular care while maintaining trust and safety.

4.4 Recommendations for safe digital integration

To balance innovation, efficiency, and safety, the EU Cardiovascular Health Plan should promote a collaborative, system-level approach through the following priority actions:

- **Support regulatory evolution through collaboration**
  Establish structured EU-level forums where innovators, healthcare providers, and regulators can share real-world data and insights. This collaboration will help regulatory frameworks such as the MDR, AI Act, and HTA processes evolve in step with technological advances.

- **Strengthen integration between safety and efficiency**
  Ensure that these frameworks support timely market access for beneficial innovations while maintaining robust safeguards. This balance is essential for both patient protection and Europe's innovation capacity.

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- **Fund real-world validation and post-market studies**
  Provide EU resources for multi-country clinical validation and post-market monitoring to generate independent evidence of safety and effectiveness under real-world conditions.

- **Promote training and simulation programmes for healthcare teams**
  Support EU-wide education initiatives that prepare professionals to integrate digital and medical innovations safely into cardiovascular pathways, with attention to ethical and professional aspects.

- **Develop EU-wide guidelines for integration and governance**
  Establish clear standards for interoperability, usability, cybersecurity, and ethical governance to harmonise practices across Member States.

- **Create a reporting and learning mechanism for technology-related harm**
  Build a system similar to pharmacovigilance to monitor, analyse, and prevent adverse events linked to digital and medical technologies, ensuring rapid feedback and learning.

- **Encourage co-design and shared responsibility**
  Promote collaboration between innovators, healthcare professionals, patients, and regulators to ensure that technologies are safe, practical, and adapted to real-world care delivery.

5. Patient and Family Engagement

5.1 Introduction: Patients as essential partners in safety

Cardiovascular care extends far beyond the hospital or clinic. Patients and their families play a central role in prevention, early detection, treatment adherence, and recovery. Lifestyle changes, medication management, monitoring symptoms, and recognising warning signs are often carried out at home, making patients and informal caregivers critical partners in the care process.

Yet, across Europe, many patients and families lack the information, training, and support needed to manage these responsibilities safely. This gap can lead to confusion, stress, and avoidable harm. When patients are discharged without clear guidance or caregivers are left to perform complex tasks without proper preparation, errors and complications become more likely.

A patient-centred approach to cardiovascular health requires recognising these realities and integrating patient and family engagement into every stage of care planning and delivery. Engagement is not a supplementary activity; it is a core element of safety and quality.

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5.2 Transitions of care: High-risk moments

Transitions of care, such as moving from hospital to home or between different care providers, are consistently identified as high-risk points for errors and communication failures.

For cardiovascular patients, these transitions often involve complex medication regimens, follow-up appointments, and lifestyle adjustments. Without clear coordination, misunderstandings can lead to missed doses or incorrect medication use, delays in seeking help for warning signs, unnecessary readmissions or complications.

Engaging patients and families as active participants during these transitions is essential to reducing harm. Providing clear, accessible, and consistent information empowers them to manage care safely and confidently.

5.3 Supporting informal caregivers

Informal caregivers, often family members take on substantial responsibilities in cardiovascular care. They may assist with medication administration, monitoring vital signs or symptoms, mobility and physical rehabilitation, emotional support and coordination of appointments.

While their role is invaluable, caregivers frequently face emotional stress, fatigue, and a lack of formal training. The burden can be overwhelming, leading to errors or even caregiver burnout.

This dynamic not only affects the safety of the patient but also contributes to workforce challenges, as unpaid caregiving increasingly fills gaps created by staff shortages in formal healthcare services.

Providing caregivers with structured support through education, respite services, and integration into care teams is critical. It ensures that their contribution enhances safety rather than introducing new risks.

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5.4 Involving patient organisations

Patient organisations bring a unique perspective to policy development and system design. They represent lived experiences, highlight emerging issues, and provide a bridge between health systems and the communities they serve.

To be effective, however, these organisations must be independent, sustainable, and meaningfully involved in decision-making processes.

When patient voices are sidelined or reduced to symbolic participation, the resulting policies risk being disconnected from real-world needs. The EU Cardiovascular Health Plan should therefore ensure that patient organisations are empowered to contribute to both the design and evaluation of cardiovascular services and policies.

5.5 Recommendations for action

The EU Cardiovascular Health Plan can strengthen patient and family engagement by promoting practical, evidence-based measures:

- **Support the creation of accessible, standardised information resources:** Fund the development and dissemination of multilingual, evidence-based educational materials on cardiovascular health, treatment pathways, and warning signs. These resources should be adaptable for Member States to use and tailor locally.
- **Facilitate harmonised protocols for care transitions:** Promote EU-level guidance and exchange of best practices to improve communication at key transition points, such as hospital discharge, ensuring patients and families receive clear, consistent, and actionable information.
- **Strengthen the role of patient organisations in policy design:** Provide EU funding mechanisms and platforms to ensure patient organisations can participate independently and effectively in cardiovascular health planning, both at the European and national levels.
- **Promote safe and inclusive digital engagement tools:** Support research and pilot projects to develop secure, user-friendly digital solutions that help patients track medications, vital signs, and appointments, while enabling safe communication with care teams across borders.
- **Encourage training frameworks for informal caregivers:** Integrate caregiver support into EU-funded projects and workforce development programmes by creating adaptable curricula and cross-border exchange on safe caregiving practices.

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By making patient and family engagement a central component of the EU Cardiovascular Health Plan, Europe can reduce avoidable harm, improve treatment adherence, and build trust between healthcare systems and the people they serve.

Empowered patients and supported caregivers are essential not only for safer care today but also for creating resilient, sustainable systems capable of adapting to future challenges.

Conclusion

The EU Cardiovascular Health Plan represents a pivotal opportunity to transform cardiovascular care across Europe. By placing patient safety at its heart, the Plan can reduce avoidable harm, protect healthcare professionals, and build trust between patients and health systems.

This is not only a matter of ethics but also of systemic sustainability. Safe care prevents waste, supports workforce retention, and strengthens resilience in the face of growing pressures on health systems.

Europe has the frameworks, expertise, and tools needed to make this vision a reality. What is now required is political will and coordinated action. By aligning with global commitments, supporting innovation, empowering patients and families, and addressing workforce well-being, the EU can set a new benchmark for safe, equitable, and sustainable cardiovascular health.

The European Patient Safety Foundation stands ready to contribute to this effort, working with all stakeholders to make safe care the defining feature of cardiovascular health across Europe.

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