INDUSTRY FORUM
INTRODUCING ESC ADVOCACY WORK
Perception and reality of cardiovascular disease (CVD)

The need to advocate for CVD
The wrong perception of CVD

- CVD is a lifestyle disease which is fully preventable
- CVD is not too bad (can be cured, not too painful, not debilitating)
- Only old, fat, smoking, alcoholic men get CVD...and it is their “fault”

CVD hits many people who live healthy lives - Genetics plays an important role
CVD remains the nº1 killer (~47% of all deaths in Europe)
CVD is closely linked to health inequalities, with more women than men dying from CVD and more CVD-related deaths in middle-income countries
The burden of CVD

- Leading cause of **mortality** in Europe: more than 4 million deaths per year
- Leading cause of **premature death** (people aged <65 years): more than 30% for men, more than 25% for women
- CVD **costs to the EU economy** over €210 billion per year: 53% for healthcare expenditure, 26% for productivity losses and 21% to the informal care of people with CVD
- Geographical **inequalities** are significant and persistent: >50% of all deaths in many middle-income countries compared with <30% in the high-income countries of western Europe
- Important differences in number of professionals, infrastructure, and **access to procedures** and services
The proportion of total deaths due to CVD ranged from 24% in Israel to 67% in Ukraine, showing huge regional differences.
There are wide disparities across Europe in access to coronary interventional procedures: Germany recorded 3,975 PCIs per million people, while Romania recorded 753 PCIs per million people.
A large disparity was observed between the various ESC member countries, as some countries, such as Egypt, Romania, Turkey and Poland, carried out fewer than 25 percutaneous transcatheter aortic valve implantation (TAVI) procedures, whereas Switzerland and Germany reported more than 150 procedures per million annually.
Ablation procedures showed enormous variations across ESC member countries ranging from <10 per million in Albania, Algeria, Kyrgyzstan and Morocco to >600 per million in Denmark, Germany and Switzerland, with an average of 58 procedures per million annually (Ratikainen T, Europace, 2015)
70M Lost Years of Healthy Life to CVD in Europe (2016)

- Cardiovascular diseases
- Malignant neoplasms
- Mental and substance use disorders
- Unintentional injuries
- Neurological conditions
- Musculoskeletal diseases
- Digestive diseases
- Chronic respiratory diseases
- Infectious diseases
- Diabetes
- Chronic kidney diseases (non-diabetic)
Projections of death rates by major causes in Europe

- Ischaemic heart disease
- Stroke
- Alzheimer disease and other dementias
- Trachea, bronchus, lung cancers
- Chronic obstructive pulmonary disease
- Colon and rectum cancers
- Lower respiratory infections
- Diabetes mellitus
- Breast cancer
- Hypertensive heart disease
- Kidney diseases

![Bar chart showing number of deaths per 100,000 people by major causes in Europe.](chart.png)

Deaths per 100,000

2030

2045

Strategic Research Agenda for Cardiovascular Diseases (SRA-CVD)
Considerable slowdown in life expectancy gains in recent years
Life expectancy fell on average across OECD countries in 2015 (first time since 1970)
Principal cause is slowing improvements in heart disease and stroke

Source: OECD Health at a Glance 2019
It’s time to end complacency and put CVD back on decision-makers’ agenda!

- Success in reducing CVD mortality is “story of the past” – CVD mortality has started to level off in several high income countries.
- More people are living longer with chronic and debilitating heart conditions for which we still have little to offer.
- With the aging population the burden of CVD is due to increase.
- CVD is closely linked to unacceptable health inequalities.
ESC Advocacy

An overview
The ESC mission « *reducing the burden of CVD* » can only be achieved if progress in science & medicine is coupled with policy and regulation supportive of cardiovascular health.
What ESC Advocacy does

- **Challenge wrong perception of CVD** & ensure decision-makers understand the burden of CVD
- **Entrench CVD as a health priority** on decision-makers’ agenda
- **Bridge science and policy** by promoting evidence-based policy
- Drive excellence and funding for **CVD research and innovation**
European Society of Cardiology: Cardiovascular Disease Statistics 2019

On behalf of the Atlas Writing Group

The ESC Atlas of Cardiology is a compendium of cardiovascular statistics compiled by the European Heart Agency, a department of the European Society of Cardiology

Developed in collaboration with the national societies of the European Society of Cardiology member countries
ESC Atlases

General ESC Atlas (2nd edition)
- 56 countries | 318 variables
- 11 sections covering general cardiology (services and interventions; health care capital resources; human capital resources; health status and risk factors; morbidity and mortality; socio-economic data linked to cardiac care)

EAPCI Atlas (1st edition)
- 35 countries | 77 variables
- 4 sections dedicated to Interventional Cardiology

HFA Atlas (1st edition)
- 42 countries | 98 variables
- 5 sections dedicated to Heart Failure
Call to Action:
Reducing the Burden of Cardiovascular Disease

✓ Atlas of Cardiology booklet to be used by National Cardiac Societies to make the case with their national decision-makers
✓ Enables national policymakers to take stock of how their country performs in several CVD indicators compared to similar socio-economic countries and identify areas of intervention for greatest impact
✓ Includes Advocacy Call to Action addressing policy makers
Press for CVD to feature on the EU agenda

Dear Ms Kyriakides,

On the occasion of World Heart Day, celebrated world-wide on 29 September, the European Heart Network (EHN) and the European Society of Cardiology (ESC) take the opportunity to bring to your attention the immense burden of cardiovascular disease (CVD) in the European Union.

Our two organisations represent cardiovascular patients and health professionals in Europe. We work to promote patient support and treatment is available to all.

Good exchange with @escardio. We need strong #HorizonEU in next #MFF to strengthen #research to fight against heart diseases, the most common cause of death in Europe. Let’s also exploit the full potential of #AI and #digital in health!
Fighting cardiovascular disease – a blueprint for EU action

Taking into consideration the competences of the EU, we propose an Action Plan on cardiovascular disease in the following areas:

- Prevention of avoidable cardiovascular disease
- More research and innovation in cardiovascular disease
- Better patient care through improved diagnosis, treatment and management

With EHN it puts forward more than 20 recommendations for actions at EU level to address the burden of CVD
1.1. Prevention of avoidable cardiovascular disease

Cardiovascular disease is often referred to as a lifestyle disease because of its causal link with behavioural risk factors (lifestyle determinants). However, given the scale of the disease, it would be more appropriate to refer to it as a societal disease.

As people are living longer, European governments are raising retirement ages to help pay for pensions and elderly care. In reality, however, many people are already disabled by ill-health before they reach retirement age. By reducing exposure to the main behavioural risk factors, tobacco, unhealthy diet, physical inactivity and harmful use of alcohol, the number of years lived in good health can be increased.

Effective population-wide interventions thus have the potential to provide both human and economic benefits with considerable returns on investment.\(^1\) Because the majority of cases come from a population at low or moderate risk of that disease and only a minority of cases come from the high risk population even a small reduction in CVD risk factors across the population will suffice to obtain the greatest societal gain (prevention paradox).\(^2\)

The following sections address lifestyle and biological determinants and one broader modifiable determinant, namely air pollution (part of living conditions).

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\(^1\) Saving lives, spending less. WHO 2018  
1.1 More research and innovation in cardiovascular disease

There is a misconception that prevention is sufficient to tackle the burden of cardiovascular disease. Effective prevention holds great potential for tackling the burden, but cardiovascular disease also hits many people who live healthy lives. New and better treatments for established CVD are needed.

Despite the burden of cardiovascular disease being greater than any other disease, research and innovation in CVD are lagging, compared with other specialties. Only one CVD medicine was approved by the European Medicines Agency in 2018.¹

The causes of this decline in innovation include low research funding in cardiovascular disease, complexity and costs of clinical trials in CVD, and an unfavorable regulatory framework for fostering CVD innovation.

¹ European Medicines Agency – Annual Report 2018
1.1 Better patient care through improved diagnosis, treatment and management

It is essential to enable people who are at high risk of developing cardiovascular disease, or who have already contracted the disease, to actively manage their condition, so that they can live to an old age with a good quality of life.

EU Member States are responsible for organising, funding and providing health care to their citizens. EU can promote coordination, share best practice and guidelines, as well as carry out non-binding initiatives.
Mobilising champions in the European Parliament

Supporters 2019 - 2024

Co-chairs of the MEP Heart Group:

- Brando Benifei MEP (S&D, IT)
- Maria Carvalho MEP (EPP, PT)

Supporters:

- Pascal Arimont MEP (EPP, BE)
- Anna-Michelie Asimakopoulou MEP (EPP, GR)
- Biljana Borzan MEP (S&D, HR)
- David Bull MEP (NI, UK)
- Isabel Carvalhais MEP (S&D, PT)
- Sara Cerdas MEP (S&D, PT)

- Letter to ~200 MEPS on the burden of CVD, the importance of EU action and offering ESC scientific input
- Letter to all MEPS on the re-establishment of the MEP Heart Group
- 40 MEPS supporters of the Group so far
Influencing the agenda of EU Presidencies

- Established ESC Task Force
- Reach out to next EU Presidencies via National Cardiac Societies
- Press for a ministerial discussion on CVD

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Making cancer-related complications and comorbidities an EU health priority

Joint statement

Cancer-related complications and comorbidities are a highly significant, and in many cases fatal, burden on patients across Europe but are all too often neglected in policy and research. ¹

Cancer is set to become a top health priority for the next five years in the EU, with both the European Commission President, Ursula von der Leyen, and Commissioner for Health and Food Safety, Stella Kyriakides, having made clear that cancer will play a central role in their policy agenda and that the output will be an EU Beating Cancer Plan.

- New multi-stakeholder initiative led by the European Cancer Patient Coalition to promote cancer-related complications & co-morbidities as an EU priority
- CVDs are one of the most frequent and serious side effects of cancer treatment
Making the case for CVD research & innovation
WHY more CV research is needed

HARD FACTS

- Research funding for CVD at national and EU level is disproportionately low compared to the socio-economic burden of CVD
  - CVD features very little in call descriptions of the EU Research Programme, and the number of EU funded projects related to CVD is fewer compared to other diseases

- Shallow pipeline of new medicines for CVD;
  - i.e. only 1 new cardiovascular drug was approved in 2017 by FDA, with same trend in EU with EMA approval

- CVD is less well understood than other clinical areas due to the complex interdependence of genetic and environmental factors
  - Further research to understand these factors is necessary
The Strategic Research Agenda for CVD

• **A blueprint to raise CVD’s profile** with decision-makers and urge for more CVD research funding at EU and national levels

• Guide priorities and identify areas of high unmet CV research need seeking to reverse the growing CVD burden

• Implementation of the proposed research agenda will require action from ministries, funding agencies, health care administrators and the private sector, at EU and national level

• Beyond the research agenda, public and private decision makers should develop novel models for care, ensure equal access to treatment and implement digital health that will in turn support research to reduce the CVD burden
Using the SRA for action at EU level

HIGH LEVEL MEETINGS

- With European Commission Director General for Health, Anne Bucher
- With European Commission Deputy Director General for Health, Martin Seychel
- With new Commissioner for Research Mariya Gabriel (03.12.19)

EMAIL CAMPAIGNS STRESSING THE ISSUE OF CARDIO-ONCOLOGY

- To key EU decision-makers including European Commissioner for Research
- To be potentially considered as a research topic under the Cancer Mission

RESPONDING TO EU CONSULTATIONS

- First online public consultation open to stakeholders – responded in September
- Second consultation through participation at the R&I Days late September
- Third consultation on Health Partnerships with industry involvement (November)
Key figures

- 540 participants
- 33 sessions
- 137 contributors to the programme
WORKING ON the EU e-health agenda

POLICY

- ESC (advocacy) member of the European Commission’s eHealth Stakeholder group providing expert advice in key areas:
  - Care continuum
  - Citizen and health data
  - Reimbursement of digital health products and solutions

EU RESEARCH PROJECTS

- CATCH ME project: New mobile app to support patient care
- BigData@Heart project: To inform on better prevention strategies for the treatment of HF, ACS, HFA
- Coming up: Coroprevention project with EAPC involvement

UPCOMING DIGITAL EUROPE PROGRAMME
ESC shaping the regulatory framework for health technologies
ESC scientific expertise supporting evidence-based regulation

✓ **Medical Devices**: ESC representation in new technical groups of the European Commission preparing the implementation of EU MDR; creation of EU MDR expert panel on circulatory diseases

✓ **Clinical Trials**: pushing for review of the international standard (ICH-GCP) for the conduct of clinical trials, working collaboratively with the Wellcome Trust

✓ **Pharmaceuticals**: ESC representation on EMA stakeholder groups & response to EMA consultations

✓ **Health Technology Assessment**: advocacy outreach to EU decision-makers in favour of EU cooperation on clinical HTA

✓ **Task Forces with EHRA & EACVI** to evaluate impact of GDPR on CIEDs and diagnostic imaging devices
MD used in CVD are of a high risk impact
We need to avoid cases of unsafe devices placed in the market

We need a robust regulatory system that ensures the SAFETY of the device and guarantees TRANSPARENCY and hence access of all information about evidence related to medical devices
Medical Devices Regulation

**2008** European Commission stakeholder consultation

**2009** European Commission starts revising legislation

**2011**
- Policy Conference
- Report: Clinical evaluation of CV devices


**2013** Position Paper

**2016** Political agreement between Council/EU Parliament/EU Commission

**April/May 2017**
- MDR final adoption & entry into force

**2017-2020** Transition phase before MDR is applicable
Cluster A (Pre-market)
- Working Group 1 *
  Notified Body oversight and Joint Actions
- Working Group 2 Standards

Cluster B (Post-market and clinical)
- Working Group 3
  Clinical investigation and evaluation
- Working Group 4
  Post-market surveillance and vigilance
- Working Group 5 *
  Market surveillance

Cluster C (Borderline and new technologies)
- Working Group 6
  Borderline and classification
- Working Group 7
  New technologies (including software, apps, cybersecurity)

Cluster D (Systems)
- Working Group 8
  EUDAMED
- Working Group 9
  Unique device identification

Cluster E (International)
- Working Group 10
  International matters

Cluster F (In-vitro diagnostic devices)
- Working Group 11
  Implementation of IVD-specific aspects of IVDR
Expert Panels on MDs and IVDs

- Establishment of expert panels to support the assessment of specific high-risk devices and to contribute to the prospective improvement of the overall framework by advising the Commission, the Medical Device Coordination Group, Member States, Notified Bodies and manufacturers.

- Circulatory system (30 experts)
Clinical Trials

What?
- CVD innovation pipeline is dry
- CVD clinical trials are particularly complex, large, long and expensive
- Average pivotal CVD trial costs 3 times more than cancer trial, 6 times more than common conditions trial

The current international rules governing the design and conduct of clinical trials are too complex and fail to produce the intended benefit for patient
**Clinical Trials: ESC initiatives**

2015 **Workshop** on the regulation and governance of clinical trials

2016 Adhered to **MoreTrials** campaign launched by the Wellcome Trust

Problem ▶ Regulation International Council on Harmonisation (ICH) Guideline on Good Clinical Practice (ICH-GCP)

Solution ▶ New guideline is needed

2017 **Opinion** on improving health by improving clinical trials guidelines and their application

2019 Expert participation on the global stakeholder meeting on ICH Guideline on General Considerations for Clinical Trials

2020 Experts in collaboration with the Welcome Trust, Bill & Belinda Gates Foundation, and African Academy of Sciences will develop GCP guidelines that are fit-for-purpose.

MSC in clinical trials

Promotion the development of patient registries in CVD
ESC interactions with EMA

• ESC is invited to provide input to/participation in general EMA activities
  • Consultations on strategic documents policies and projects
  • Conferences and workshop

• ESC Individual Experts are requested to input into product-specific consultations, subject to confidentiality
We need to improve patient access to effective novel healthcare technologies.
ESC research shows that there are huge disparities between countries concerning the availability of cardiovascular care.

A robust HTA system led by experts will help decision makers to adopt evidence-based policies.

Improving cooperation on HTA at European level may help bridging gaps between countries.
Health Technology Assessment: ESC initiatives

2010-2012 / 2012-2015 / 2016-2020 EUnetHTA 1,2 & 3

Participation in EUnetHTA 1 & 2

2013 Commission creates the HTA Network

Part of the HTA Network stakeholder pool

2018 Commission proposal Regulation on Health Technological Assessment

06 & 07/2018 Expert’s contribution to EP and Commission organised debates

06 & 11/2018 Contact with the Bulgarian and Romanian Presidencies of the Council

06 & 10/2018 Position Papers
Health Technology Assessment: ESC initiatives

European doctors unite to demand policymakers’ support for EU-level HTA

While the European Parliament (EP) prepares to vote upon the legislative proposal on health technology assessment (HTA)1, organisations representing tens of thousands of healthcare professionals who make daily use of health technology unite in a call for a prompt legislative outcome.

The European Society of Cardiology (ESC) together with the European Academy of Neurology (EAN), the European Association for Cardio-Thoracic Surgery (EACTS), the European Association of Urology (EAU), the European Federation of National associations of Orthopaedics and Traumatology (EFONT), the European Respiratory Society (ERS), the European Society of Anaesthesiology (ESA), the European Society of Endocrinology (ESE), the European Society of Human Reproduction and Embryology (ESHRE), and the European Union of General Practitioners (UEMG) strongly believe that a collaborative framework for the clinical assessment of health technologies is necessary to support high-quality healthcare in Europe. Only a robust system relying on best evidence, and built in the true EU spirit of equity, collaboration and transparency is suited to bring added value to EU patients. This is why European doctors demand policymakers’ support for EU-level HTA without delay.

1 Present for a regulation of the European Parliament on the Database for health technology assessment and an evaluation directive 2011/66/EU

European Society of Cardiology

Statement: European Parliament vote on health technology assessment (HTA)

The European Society of Cardiology (ESC) together with the European Respiratory Society (ERS) strongly believe that HTA is fundamental to high-quality healthcare in the EU.2

Today, we commend Members of the European Parliament for the adoption of the legislative proposal on health technology assessment’ (HTA).2

2 Present for a regulation of the European Parliament on the Database for health technology assessment and an evaluation directive 2011/66/EU
The ESC Patient Forum
Patients as advocates
Patient Advocacy

Giving a voice to patients, survivors of an illness and caregivers

Among typical Patient Advocacy activities are:

• Defending the rights of a patient
• Education of patients and their families
• Education of healthcare providers
• Support and information
• Patient representation
• Building awareness
• Access to healthcare, medicines and technologies
ESC Patient Forum – where do we stand?

• ESC Patient Forum established in June 2018

• Currently around 24 members from 12 European countries with personal experience of different heart conditions (CAD, CHF, CHD, arrhythmias, CIEDs, ...)

• Patients are involved in their personal capacity, not as representatives of patient organisations

• They are involved in ESC activities as task force members, speakers/chairs, discussants, reviewers, co-authors, ...
Why Patient Engagement in ESC Advocacy?

• Patient advocacy plays a crucial role in changing decision-makers’ perception of health conditions.

• The patients’ experience is invaluable to better understanding their challenges, needs, expectations and hopes.

• Patients have an authentic passion & ability to transform the narrative to one of compassion.

• The right story can have the power to motivate and change minds.
CVD patient advocates have not been as vocal or coordinated as in other disease areas. We will leverage the “patient’s voice” in our advocacy activities through the ESC Patient Forum.

**Planned activities:**

- Patients speaking at ESC Advocacy events in the European Parliament
- Patient’s voice to be reflected in ESC Advocacy materials
- Patient’s testimonials promoted via social media & communications targeting key decision-makers
Living with a heart condition

In the light of the launch of five new ESC Clinical Practice Guidelines at ESC Congress 2019, members of the Patient Forum share their experiences of living with chronic coronary syndrome, SVT and pre-diabetes.
“Tell me a fact and I’ll learn. Tell me a truth and I’ll believe. But tell me a story and it will live in my heart forever.”

North American Indian proverb

Thank you very much!