

## Italy



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#### About the Heart Failure Policy Network

The Heart Failure Policy Network (HFPN) is an independent, multidisciplinary network of healthcare professionals, advocacy groups, policymakers and other stakeholders from across Europe. It was established in 2015 with the goal of raising awareness of unmet needs and seeking meaningful improvements in heart failure policy and care. Our aim is to help reduce the burden of heart failure – on people living with it, those supporting them, health systems and society at large. All members of the HFPN provide their time for free. All Network content is non-promotional and non-commercial. The Secretariat is provided by The Health Policy Partnership Ltd, an independent health policy consultancy based in London, UK.

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# **About** Heart failure policy and practice in Europe

Heart failure (HF) is a common and complex condition responsible for extensive avoidable morbidity, mortality and healthcare costs. There is a clear need to advance HF policy and practice across Europe, and this requires recognition of the real challenge in each country.

To this end, the Heart Failure Policy Network (HFPN) has developed *Heart failure policy and practice in Europe* – a comprehensive analysis of key gaps and best practice both in HF policy and in clinical performance across 11 European countries. In this work, we investigate each country's progress in addressing the HF challenge, for example in terms of the existence and implementation of HF policies and the provision of multidisciplinary and integrated HF care. Findings are presented in an overarching report, which outlines the methodology for this work and includes a pan-European narrative, and in standalone country profiles with dedicated national-level analysis.

Urgent action is needed to address the growing burden of HF and ensure the sustainability of our healthcare systems. This country profile aims to assist HF advocates across Italy in engaging healthcare system leaders to demand constructive changes to HF policy and care provision, to reduce the impact of HF on people living with the syndrome, their families and carers, the healthcare system and society.

## **Heart failure** in Italy

#### **SUMMARY**

The burden of heart failure (HF) in Italy is high. HF is the second leading cause of hospital admissions, rehospitalisation is frequent, and healthcare costs for HF are significant. <sup>2-4</sup> The overall burden is growing, putting pressure both on the healthcare system and on the economy. Recently, the Italian government has declared HF as one of the most important healthcare issues in Italy. <sup>5</sup>

Policymakers increasingly recognise the importance of HF, as demonstrated by the inclusion of HF in the National Plan for Chronic Conditions. <sup>56</sup> In addition, clinical guidelines have been published to support people living with HF. <sup>7-10</sup> However, the organisation of healthcare in Italy determines regional implementation of health policies and guidelines, which has led to national variation in HF care delivery. <sup>11 12</sup> Furthermore, the COVID-19 pandemic may have impacted the implementation of healthcare plans. <sup>12</sup>

National experts have called for improvements in early diagnosis,<sup>12 13</sup> hospital care and discharge,<sup>14</sup> and community-based HF care<sup>14 15</sup> to achieve better outcomes for people living with HF and reduce its societal burden in Italy.

## HF is a common syndrome with increasing prevalence

HF is one of the most important health issues in Italy,<sup>5</sup> with an estimated prevalence of 1.4% of the population in 2009.<sup>16</sup> The prevalence of HF increases with age<sup>2</sup> – it is believed that it affects nearly 15% of people aged 85 and older.<sup>4</sup> Considering that Italy has the second highest number of people over the age of 65 in the world,<sup>17</sup> this high incidence rate is particularly concerning.



HF prevalence

### HF is associated with high expenditure

HF imposes a significant economic burden on the health system and society – an estimated 2.4% of the national healthcare budget is related to HF management.² In 2012, the total cost of HF was estimated at almost USD \$4 billion (a little over €3 billion).³ Direct costs were estimated to account for almost 70% of this, with the remainder made up by indirect costs, such as those linked to sickness benefits and welfare support. In 2013, total annual



**HF** total cost

expenditure per person with HF was estimated at €11,864, with hospitalisations accounting for 76% of this cost.<sup>4</sup>

HF often requires hospitalisation and leads to poor outcomes

In Italy, HF is the second leading cause of hospitalisation, after childbirth. There are roughly 200,000 HF hospitalisations per year, of which 88% are in people over the age of 65. Although there are gaps in available data, the historical picture is one of concern. In 2010, the median length of hospital stay for people with HF was 10 days, with nearly half admitted to intensive coronary care for four days. 19



hospitalisations per year

Mortality is high, with reports suggesting that on average 7% of patients die during their first hospitalisation.<sup>20</sup> Within one year of discharge, 24% of people with HF die and 59% are rehospitalised.<sup>20</sup> In addition, data from 2005 have shown that, historically, HF contributed to a significant proportion of hospital admissions deemed likely to be preventable, ranging from 29% to 47% depending on the region.<sup>21</sup>

National experts have expressed concerns about the long-term impact of the COVID-19 pandemic on people living with HF due to the disruption of services and care. <sup>22 23</sup> During the pandemic, emergency departments saw a decline in the number of people presenting with symptoms of acute HF. For example, in one hospital in Rome, admissions during a period of two months in the early phase of the pandemic dropped by nearly 50% when compared with the same period in 2019. <sup>23</sup> Those who did present were more likely to die in hospital or experience a serious decline in health, possibly owing to barriers in accessing appropriate care during the pandemic. <sup>23</sup>



## **Heart failure policy** in Italy

### Formal plans on HF

#### In the absence of a formal HF plan, Italy has recognised the need to address HF in broader healthcare strategies

The Italian government has yet to develop a dedicated plan on HF. However, in 2016, the Ministry of Health launched the National Plan for Chronic Conditions (Piano Nazionale della Cronicità), which outlined a strategy to improve HF management, particularly in primary care settings. <sup>56</sup> The plan acknowledged the burden of chronic HF and called for continuity of care and the implementation of care pathways for complex HF cases, among other things.

Other policy initiatives hold promise in advancing HF care. National health strategies, currently called the Pact for Health (Patto per la Salute),<sup>24</sup> have for some time recognised the importance of reducing hospitalisations and improving quality of life for people living with HF.<sup>25</sup> The Ministry of Health publishes National Prevention Plans (Piani Nazionale della Prevenzione, PNPs) to promote health and prevent disease.<sup>26</sup> The PNP 2020–2025, launched in July 2020, focuses on the integration of policies and strategies relevant for healthcare at a national, regional and local level, promoting a 'health in all policies' approach.<sup>27 28</sup> The plan defines five 'macro objectives', including addressing non-communicable diseases, calling for their multidisciplinary and integrated management. While commendable, this plan does not include specific actions for the different areas of healthcare, including HF.

## Adoption of national healthcare strategies varies with regions, contributing to variation in HF care

Implementation of healthcare plans falls to regional governments, which inevitably leads to significant national variation in healthcare delivery. The National Plan for Chronic Conditions, for example, was followed by policy plans in 15 regions, with the five remaining regions yet to complete theirs.<sup>29</sup> However, differences

have been noted between the regions with regard to the timing and sometimes inconsistent implementation of national health plans.<sup>29</sup> Overall, northern regions of Italy have been more successful in putting these plans into action than regions in the south, which has been attributed not just to the regional health systems but also to political, economic and cultural differences.<sup>11</sup> National experts believe that the COVID-19 pandemic may have further delayed the implementation of healthcare plans.<sup>12</sup>

## Investment in integrated HF models and facilitative tools

#### HF diagnostic tests are consistently reimbursed

Experts state that core HF diagnostic tests – including natriuretic peptide (NP) testing and the gold standard, echocardiography<sup>30</sup> – are typically reimbursed across all care settings, but inequalities in access still arise across regions.<sup>12</sup> This is partly attributed to the fact that, while the Ministry of Health makes central recommendations for reimbursement rates, funding policies are determined by each region independently.<sup>31</sup>

#### The healthcare information system enables national analyses, but collects insufficient clinical data to assist in integrated care

Experts state that the healthcare information technology (IT) system allows for data linkage, with data being processed by the Ministry of Health. However, analyses are mostly performed for administrative purposes, with few regions (such as Lombardy and Emilia-Romagna), as well as the Cineca collaborative (a not-for-profit national consortium of universities and public institutions), using the data for clinical research. Experts report that for the first time, as part of the National Plan for Chronic Conditions, the Ministry of Health will use the administrative data to evaluate indicators of care processes and monitor quality of care. The collection of additional clinical parameters, such as ejection fraction and cardiac biomarker levels, would allow the IT system to contribute to a better understanding of HF care in Italy.

## Government interest in telemedicine is growing, with implementation in HF yet to become a reality

Italy has seen growing interest in telemedicine. The National Plan for Chronic Conditions recognised the importance of the use of telemedicine in preventing exacerbation and progression of HF.<sup>5</sup> However, the 2014 National Guidelines on Telemedicine by the Ministry of Health, which outline the potential for innovative technology to transform the future of healthcare delivery, including in cardiovascular disease, do not specifically mention HF.<sup>33</sup> In addition, they have yet

to be implemented, mainly due to lack of alignment between national and regional decision-makers (not least on funding).<sup>8 34</sup> Experts highlight that the COVID-19 pandemic has increased awareness of the importance of remote monitoring in chronic disease management, including HF.<sup>14</sup> They add that multiple patient associations, including those representing people living with HF, have recently submitted a formal letter to the Ministry of Health urging it to accelerate the introduction of telemedicine into current clinical practice.<sup>14</sup>

### Development of the HF healthcare workforce

#### National professional societies offer training in HF, but HF specialisation is not officially recognised

National experts state that there is no formal accreditation of HF specialist physicians or nurses;<sup>12</sup> however, national professional societies provide HF training to healthcare professionals. The National Association of Hospital Cardiologists (Associazione Nazionale Medici Cardiologi Ospedalieri, ANMCO) identified a desire among cardiologists for certification in advanced HF,<sup>35</sup> and in collaboration with the University of Florence is running a one-year Master's degree in HF for physicians.<sup>36</sup> In addition, it is working to raise general levels of professional awareness via 'summary cards' featuring essential information on HF diagnosis and management in line with recommendations in the 2016 European Society of Cardiology (ESC) guidelines.<sup>37</sup>

General practitioners (GPs) have also expressed a need for greater training to diagnose and manage HF.<sup>13</sup> As yet, however, is it unclear whether any suitable programme exists. The National Centre for Disease Prevention and Control (Centro Nazionale per la Prevenzione e il Controllo delle Malattie) and the Ministry of Health developed a training course for GPs and other healthcare professionals to improve expertise in cardiovascular risk.<sup>38</sup> However, the curriculum does not include a module on HF.<sup>38</sup>

Experts report the recent creation of a national association focused on HF – Italian Heart Failure Association (ITAHFA)<sup>39</sup> – which, among other objectives, will aim to support the development of multidisciplinary HF teams.<sup>14</sup>



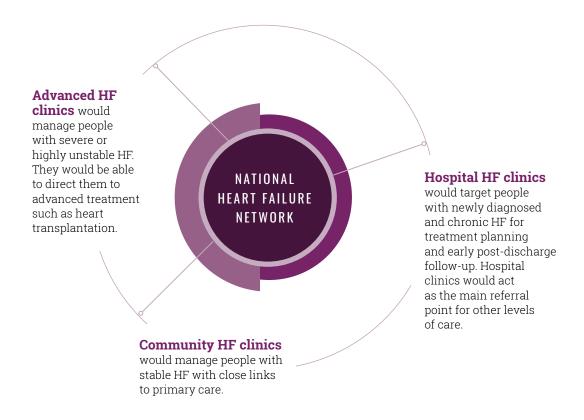
## Guidance and local care pathways for delivery of quality care

## Guidance has been developed by professional societies to reduce fragmentation of care and promote optimal HF management

Italy has a comprehensive guidance framework promoting multidisciplinary and integrated HF care. The Italian Federation of Cardiology has formally endorsed and translated the 2016 ESC HF guidelines. <sup>12 40</sup> Professional societies (including the ANMCO, the Italian Society of Cardiology (Società Italiana di Cardiologia, SIC) and the Italian Society of Internal Medicine (Società Italiana di Medicina Interna)) have published various joint consensus documents to promote best practice in HF care. These include a protocol for acute HF from symptom onset to hospital discharge, <sup>9</sup> recommendations for the provision of palliative care for people with HF, <sup>10</sup> and the promotion of telemedicine-based care models in HF. <sup>8</sup> Professional societies have also developed non-HF-specific guidance with the potential to improve HF care, including a position paper from ANMCO on discharge planning for patients admitted to cardiology units. <sup>41</sup>

In 2017, the ANMCO and SIC published a consensus document aiming to improve outpatient HF care through better integration. The document proposed a national HF network with clear links between healthcare professionals working at three different levels of care: community HF clinics, hospital HF clinics and advanced HF clinics (*Figure 1*). The network aims to integrate in-hospital and outpatient care with the activities of other healthcare professionals, such as GPs and social care workers, to ensure seamless continuity of care. It is unclear, however, whether implementation of this pathway for outpatient HF management has been initiated.

 $FIGURE\ 1.\ \textbf{Cardiology network for outpatient heart failure\ care}^{7}$ 





## Public audits of performance and high-level assessment initiatives

#### Several registries monitor different aspects of HF care, but the lack of a national registry holds back full oversight of unwarranted variation

There is no national registry allowing for a comprehensive assessment of HF care services and patient outcomes. Various registries have been set up to characterise the HF population and care, including the multicentre Italian Network on Congestive Heart Failure (Il Registro Italiano dello Scompenso Cardiaco),<sup>42</sup> which later became the Italian Network on Heart Failure.<sup>43</sup> <sup>44</sup> The ARNO Observatory, a population-based database that collects and integrates national health system data for every patient, has been used to investigate HF outcomes and link them to expenditure.<sup>4</sup> Another multicentre initiative, Hormonal Treatment in Heart Failure (Trattamento Ormonale nello Scompenso Cardiaco), aims to improve the understanding of interactions between hormonal treatments and chronic HF.<sup>2</sup>

While data in these registries are valuable, there are significant limitations to what can be achieved from independent registries that do not cover the entire HF population. Several challenges have been cited as potential barriers to the development of a comprehensive registry, including the difficulties of developing a platform where all relevant data can be collected and the need for data to be added by a wide range of healthcare professionals. According to experts, the recently created ITAHFA will aim to address this data collection gap. 4



## **Heart failure practice** in Italy

## **Diagnosis**

The diagnosis of HF is delayed by limited recognition of HF symptoms, suboptimal use of NP testing and long waiting times for echocardiography

HF diagnosis is often delayed. GPs are typically the first point of contact for people with symptoms of HF and refer patients to cardiologists when HF is suspected. 12 However, limited awareness of preclinical HF signs and symptoms may delay referral and management of HF. 14 45 In addition, experts state that NP testing is not consistently used to guide the referral pathway and there are typically long waiting times for echocardiography, particularly in the southern regions, all of which hinders timely diagnosis. 12 13

### Hospital care and discharge

Acute HF management is well organised, with improvements needed in discharge planning, NP testing and post-discharge care

The medical specialist leading the management of acute HF varies – cardiologists are reported to lead care in just over a quarter of cases, with other specialists, including internists, geriatricians and intensive care specialists, in charge of the others. Experts report that referral from emergency to other hospital departments is often well managed, but there is a need for better understanding of the value of NP testing in hospital settings. 14

Experts further state that hospital discharge and post-discharge care for people with HF is not consistently of high quality. This is supported by historical data showing limited alignment of prescription practice with guideline-based recommendations at hospital discharge, and a need for improvement of discharge and post-discharge care. For example, GPs have reported repeatedly receiving hospital discharge summaries that are missing key information such as NP testing results.



Furthermore, experts report long waiting lists for HF clinics and emphasise that scheduled follow-up appointments with a cardiologist do not regularly occur within two weeks of discharge, as recommended in guidelines.<sup>12</sup>

## Key components of quality care in community settings

## Organisation of HF care does not consistently include key elements of best practice

Several aspects of HF management need improvement. For example, it has been reported that too often HF medications are not prescribed in line with best-practice recommendations. $^{746}$ 

Despite the expansion of HF clinics in the past decade, their number is insufficient to support all people living with HF.<sup>12</sup> The clinics may also need better referral and communication linkages with a wider range of healthcare professionals, especially in the primary care setting.<sup>47</sup> Experts highlight that telemedicine models are needed to ensure high-quality care for all people with HF, such as those living in remote areas.<sup>14</sup>

#### Cardiac rehabilitation is not consistently provided for people with HF

Cardiac rehabilitation was cited as a priority by leading clinicians in 2015.<sup>25</sup> Currently, there are widespread differences in the provision of cardiac rehabilitation between and within regions, and provision overall remains largely insufficient, despite some improvements.<sup>12</sup> Beyond capacity, barriers are reported to include a lack of awareness among healthcare professionals of the recommendations for rehabilitation in the management of HF and insufficient referral.<sup>14</sup> <sup>15</sup>

## Patient education and support for self-care is not standard practice in HF care

Self-care education and patient empowerment are not consistently offered in HF management,<sup>48</sup> with experts stating this is mostly due to the constraints of a heavy workload.<sup>14</sup> Experts suggest that this is an area in need of urgent intervention,<sup>15</sup> with a recent pilot highlighting the benefits of nurse-led self-care improvement programmes.<sup>48</sup> In efforts to address the absence of consistent self-care education, the Italian Association for Heart Failure (Associazione Italiana Scompensati Cardiaci, AISC) provides guidance and support to people living with HF (see *Case study 1*).<sup>14</sup>



## A model for promotion of self-care education and patient empowerment

The Italian Association for Heart Failure (Associazione Italiana Scompensati Cardiaci, AISC) has developed different models of self-care education and patient empowerment. It has produced educational materials on what HF is and how to follow treatment, including dietary and physical activity regimens. It runs an itinerant programme of awareness and support,<sup>49</sup> with on-the-spot specialist consultations available. People with HF can contact experts for advice directly through the AISC website.<sup>14</sup> The association works closely with a number of hospitals to link volunteers with people with HF before discharge. AISC volunteers may visit people in hospital or cardiac rehabilitation centres and offer targeted support.

According to AISC, this model has resulted in improved outcomes.<sup>14</sup> While it helps to ensure people living with HF and their families/carers are supported to self-care, there is room to further enhance coordination with clinicians to ensure integration of care.

#### There is limited provision of psychological support and palliative care in HF

Experts state that psychological support is not easily accessible for people with HF – it is generally available only for those treated in HF-specific settings. <sup>15</sup> Palliative care is also widely unavailable as it has traditionally been reserved for people living with cancer, with few people with non-malignant illnesses accessing the service. <sup>50</sup> Barriers to palliative care in HF include uncertainty among healthcare professionals, people living with HF and their families regarding its value. <sup>10</sup>

## Tools and methods to support multidisciplinary and integrated ongoing HF care

## Centres of excellence offer various tools and models to encourage multidisciplinary HF care, which are largely unavailable in other settings

Experts state that HF care is not consistently integrated or multidisciplinary, and the involvement of healthcare professionals across settings is often only available on request. However, there are successful models of integrated HF care in selected regions, such as Bergamo and Trieste, where care is multidisciplinary and includes home visits and telemedicine appointments to support transition from hospital to community care. In Trieste, a clinic focusing on management of advanced HF



provides person-centred and integrated care, including palliative care, along with support to the family.<sup>51 52</sup> These models could benefit from wider roll-out to improve the response to the HF challenge.

#### Telemedicine has proven successful in supporting management of HF

National studies have shown the benefits of telemedicine, in terms of both feasibility and patient adherence, in the stabilisation of HF symptoms and the reduction of hospital readmissions and associated healthcare costs. <sup>53 54</sup> At the beginning of the COVID-19 pandemic, a seven-week pilot telemedicine service, which included 24/7 phone access to healthcare professionals with chat and videoconferencing options, reduced HF hospitalisations and deaths compared with the same period in 2019. <sup>22</sup> This highlights the value of telemedicine as an important tool for the management of HF and its potential in supporting integration of care moving forward.

## The way forward

HF poses a challenge to the sustainability of healthcare systems in countries across Europe, including Italy. It is a manageable – and often preventable – syndrome, yet it continues to affect a great number of people and its burden on the national health system and society is significant.

Policymakers in Italy have started to recognise the impact of HF and the need to address it, but there is still an urgent need for a robust response to the challenge HF poses. This has been underlined by the recent impact of COVID-19 on the healthcare system.

#### SEVERAL ACTIONS ARE ESSENTIAL TO ADDRESS THIS CHALLENGE.

**Expand** expertise in HF among the healthcare workforce and promote collaboration with patient associations to offer self-care education

Greater public investment is needed to build skills and capacity in the HF healthcare workforce. Better expertise is required along the entire HF care journey to improve diagnosis, hospital care and discharge, and care in the community. Training opportunities led by national professional societies can support the correct identification of HF signs and symptoms as well as optimal management of HF, both acute and chronic, in line with the latest best-practice recommendations. It is also crucial to support people with HF understand their condition and how best to manage it. Clinicians have a heavy workload and often lack the time to empower patients (and their families or carers) to self-care. The model developed by the patient association AISC has demonstrated the benefits of allowing patient organisations to focus on providing the non-clinical aspects of self-care education.

**Improve** HF diagnosis through increased use of NP testing and faster access to echocardiography in primary care

Improving diagnosis is a crucial step in a coherent response to the HF challenge. For this to happen, it is essential for primary care professionals to consistently access and use NP testing and for echocardiography to be easily accessible. Increased use of NP testing will help to prioritise referrals for specialist-led echocardiography, which will likely reduce waiting lists for specialist examinations and help address this significant bottleneck in the diagnosis of HF. Professional bodies, particularly primary care societies, can help improve understanding of the value of NP testing in HF and support the accurate use and interpretation of diagnostic tests via training.

#### Accredit and fund the HF specialist nurse role

It is essential that the HF specialist nurse role be formally recognised and accredited and that specialist nurses be closely involved in the management of HF. Nursing societies can guide efforts to standardise requirements in terms of education and clinical responsibilities. These criteria can then be incorporated into postgraduate training programmes, which should be formally recognised by the regional and national healthcare systems and professional societies. Accreditation should be linked to financial recognition of the role to foster interest in the specialisation, which will likely support the development of an HF specialist nursing workforce and may support incorporation of these professionals into multidisciplinary HF care teams.

**Enhance** the existing IT system to allow for communication across care settings and the development of an HF registry enabling oversight of care

There is a clear need for an IT system that fosters communication between healthcare professionals and settings, and enables the assessment of regional and national performance. The current national system already allows data to be shared, but it should be expanded to incorporate a short set of quality indicators for HF, to assist the creation of a truly national, ongoing registry. This would help identify gaps and best-practice approaches, and could enable far greater integration of HF care.

**Promote** multidisciplinary and integrated HF care though the development of an HF network and a more comprehensive model of funding

National professional societies have laid the groundwork for improvements through the development of comprehensive HF guidance and recommendations for the organisation of care. It is now important that care and funding structures support the proposed models. In particular, implementation of the HF network proposed by ANMCO and SIC would support the organisation of care, promoting integrated management of HF. In addition, the network should help to lead the implementation of telemedicine for HF care to help ensure better care for people in remote areas and reduce risks and costs from unnecessary visits to care settings. To ensure equality in HF care across the country, national government bodies should support regions to implement the HF network as well as revised funding models.

Focusing on these priority areas will likely offer a cost-effective opportunity to improve life for people with HF, reduce hospitalisations and mitigate future pressures.

This is an investment in a more resilient and prepared health system, not just for HF but for chronic diseases more generally.

The creation and maintenance of national strategies and plans in HF is likely to be vital to long-term success. There are many strengths and existing resources within the healthcare system on which to build. Lasting success will require effective central oversight of inequalities and unacceptable variations, as well as long-term collaboration and commitment from decision-makers, patient representatives, healthcare professionals and the private sector. Failure to pursue the actions recommended in this report will allow HF to continue to challenge the sustainability of the healthcare system in Italy.

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