

From guidelines to action

Opportunities for heart failure advocacy in Italy



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About this document

The Heart Failure Policy Network (HFPN) is developing several country-specific heart failure (HF) advocacy briefings that identify existing tools and mechanisms available to drive system change at the national and local levels.

The briefings build on our previous work, particularly <u>Heart failure policy and practice in Europe</u> and its accompanying country profiles, which highlight policy and system gaps in heart failure. They are part of a new series exploring barriers to and opportunities for implementing evidence-based HF care, inspired by *From guidelines to action: opportunities for change following the 2021 ESC guidelines*.

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1. Actions for heart failure advocates in Italy

By taking a closer look at heart failure (HF) policy and extracting key insights from local pioneers, the HFPN aims to support HF advocates in maximising opportunities to improve the lives of people with HF. We hope that the specific actions proposed in this briefing can help drive system change for HF at the local, regional and national levels in Italy.

Advocacy opportunity	Action
Development and delivery of national and regional strategies on cardiovascular health	 Call on regional authorities to develop comprehensive regional plans and implementation strategies for chronic disease, including HF Call on national and regional authorities to ensure funding is available for tackling staff shortages in HF care
Monitoring of quality indicators for people with HF	Call on national and regional health authorities to harness data for improving the quality of care for people with HF
Circulation and implementation of HF care guidance	Call on regional health authorities to (further) develop structured care pathways specific to HF and make patient empowerment part of these pathways
Investment in the digital transformation of the health system	Call on regional authorities to develop guidelines that set out clear standards for the provision and use of telemedicine services for HF to ensure access to high-quality care
	 Call on health authorities to leverage telemedicine to address inequalities in access to HF care and improve care standards

2. Heart failure burden and the health system in Italy

Heart failure places a substantial burden on the Italian health system and on people living with the syndrome

In Italy, data from 2012 suggest that 1.7% of the general population and almost 15% of people over the age of 85 are living with HF.¹ A significant proportion of people with HF (7%) die during their first hospitalisation.² Within one year of discharge, 24% of people with HF die out of hospital and 59% are rehospitalised.² Evidence points to huge regional variations in the provision of care, with the percentage of people who adhere to HF medication ranging from 2% to 70%.³

For more information about the context of HF policy and practice in Italy, please see <u>Heart failure policy</u> and practice in Europe: Italy.

Driving change in the Italian health system

The Italian National Health System (Servizio sanitario nazionale, SSN) is universal and provides most health services free of charge. Any Italian citizen or legal resident has the right to access the SSN and its wide range of services.⁴ Most Italians make use of this right, with private health insurance only accounting for 2.8% of total health spending.⁴ General practitioner (GP) visits are free, but partial payments, known as co-payments, are required for specialist visits, diagnostic procedures and, in some regions, pharmaceuticals. An upper limit is set for these co-payments (€36.15 in 2020)⁵ and certain groups, including people aged over 65 in households with an income below €36,000 per year, are exempt.⁵ Nonetheless, in some regions, people report unmet medical needs owing to lack of financial resources, lengthy waiting times for visits and examinations, and long travel distances to access services.⁴

Evidence suggests that the quality of care offered by the SSN can vary widely between regions. The central government sets the main principles and strategic objectives for health via the Ministry of Health, but each region is responsible for organising and delivering healthcare services through a network of local health authorities (Aziende Sanitarie Locali, ASLs) and public and private providers. ⁴⁶ This has resulted in variability in the provision of health services, with sometimes significant gaps in service quality between regions. In many cases, these gaps mirror socioeconomic disparities, with northern regions generally faring significantly better than those in the south. ⁶

Based on Italy's current health policy, research analysis and expert opinion suggest that focus is needed at the regional level to drive the implementation of HF guidelines and policies. HF is recognised as a strategic priority in the national plan for chronic conditions, but implementation is patchy across regions.⁷ As a result, regional decision-makers need to take ownership of the HF strategy and drive its implementation.

3. Advocacy opportunities for optimising heart failure care

Development and delivery of national and regional strategies on cardiovascular health

Local and regional HF advocates can invoke the National Plan for Chronic Conditions to garner the support of decision-makers and ensure regional implementation.

HF has been prioritised in national health policy. The 2016 National Plan for Chronic Conditions (Piano Nazionale della Cronicità, PNC) proposes a concrete strategy to improve HF management.⁸ Citizen-patient associations have been involved in writing the PNC and facilitating its implementation.⁷ In 2018, most regions reported that the implementation of the plan was ongoing, with different levels of progress being reported.⁹ The proposed strategy, which includes several interventions for HF, is to promote:⁸

- the implementation of Diagnostic-Therapeutic-Assistance Paths (Percorsi Diagnostici Terapeutici Assistenziali, PDTAs*), which are structured care pathways for people with HF that span primary, secondary and tertiary care and aim to support healthcare professionals in providing best-practice care
- an organisational model that ensures hospital departments and local services work together to provide integrated care management in HF
- professional collaboration to improve support within and outside the hospital and in dedicated outpatient clinics, particularly for people with advanced HF who require more complex treatments or cardiac devices
- the adoption of home assistance and/or tele-assistance mediated by telemedicine (televisit, teleconsultation, telemonitoring) to monitor vital signs, predictors of deterioration, or both.

Clinical leaders in Italy are aiming to advance HF care via national collaboration, but these efforts are not yet supported by all regions. The Working Group on Heart Failure of the Italian Association of Hospital Cardiologists (ANMCO) and the Italian Society of Cardiologists (Società Italiana di Cardiologia, SIC) drafted a guidance document for the organisation of a national HF care network in 2017. This document proposed the integration of cardiology specialist services into multidisciplinary and multi-professional care pathways. It also outlined protocols and communication systems for HF clinics in community, hospital and specialist care settings. The guidance aimed to lead to a network that could facilitate better continuity of care at different stages of the disease while also responding to people's needs and being cost-effective. However, an Italian expert noted that the network is not yet operative in all regions.

The SSN is facing staff shortages that are reportedly a major barrier to providing best-practice care, including for people with HF. Major staff shortages have been reported as a continual issue for the SSN, resulting in a lack of medical staff and long waiting times and travel distances.¹²

^{* &#}x27;A predefined, articulated and coordinated sequence of services provided on an outpatient and/or hospitalisation and/or territorial level, which provides the integrated participation of different specialists and professionals (in addition to the patients themselves), at the hospital and/or territorial level, in order to carry out the diagnosis and the most appropriate therapy for a specific pathological situation or even healthcare.'10

Naturally, this affects HF care as well. The governors of administrative regions have made a series of urgent requests to the newly elected Italian government to address the lack of personnel. However, increasing the number of healthcare personnel would require changing the legal framework that imposes spending ceilings and limitations on the employment and management of these professionals.¹³



Action: call on regional authorities to develop comprehensive regional plans and implementation strategies for chronic disease, including HF

With regions being responsible for the local-level implementation of the PNC and its strategy for HF, advocates should call on regional authorities to:

- commit to the development of a regional plan for chronic conditions that includes HF
- **use data collected on HF** to assess regional needs and challenges in HF care and inform regional strategic priorities
- set up a working group to drive the implementation of an HF regional strategy as part
 of a regional plan for chronic conditions, allocating specific actions to working group
 members
- **nominate implementation leaders**, such as general managers, who can allocate assets and define priorities and local care pathways.



Where has this approach succeeded?

To drive the implementation of the PNC, the region of Umbria approved its own plan for chronic diseases, including HF, in 2017. Furthermore, the region gave the general managers of regional health authorities the mandate to implement or redesign clinical care pathways to be in line with the national plan. It also gave a mandate to the Regional Director of Health, Welfare Organization and Human Resources to set up working groups for the progressive implementation of specific actions.³

The plan has a section dedicated to HF. It proposes an integrated model of care based on stratification of risk. The main directions of action include:14

- promoting the dissemination and implementation of the regional PDTA for HF (for which details are provided in the same plan)
- implementing a regional network for the integrated management of HF
- providing specific training for all personnel involved and promoting a collaborative approach to care both in and out of hospital
- making the general population and service operators aware of the existence and purpose of the management network and how to access it
- promoting telehealth.



Action: call on national and regional authorities to ensure funding is available for tackling staff shortages in HF care

HF advocates could:

- demand that authorities increase investment in the health workforce to tackle the significant backlog caused by the COVID-19 pandemic, which has an impact on care for people with HF
- urge authorities to reaffirm the role of GPs in managing chronic diseases, which could include HF, in line with the latest Pact for Health for 2019–21¹⁵
- insist that authorities address the rapidly declining number of nurses, as Italy already
 has one of the lowest numbers of nurses per capita among Western European countries⁴
- **demand an increase in the number of specialist nurses for HF** to tackle both the patient backlog in HF care and staff shortages in this area
- promote an increased awareness of the central role that nurses can play in implementing multidisciplinary care models at the local level¹⁶ and in using telemonitoring tools¹⁷ to support self-care in patients and potentially increase their self-reliance.

Monitoring of quality indicators for heart failure

Quality indicators are essential to monitor heart failure and inform policies. Existing national efforts have uncovered astonishing variation in care across regions, which leads to inequalities that must urgently be addressed.

Various organisations collect quality indicators for HF at the national level. The IN-heart failure network registry coordinated by the ANMCO Research Centre is a nationwide database that compiles data on epidemiology, clinical characteristics and the management and outcomes of people with HF in the outpatient setting. The PNC proposed using the percentages of people who are in home care, being followed at home and receiving remote assistance as quality indicators for HF.8

Quality indicators used by national health authorities have been integral in uncovering worrying inequalities. National health authorities use two indicators to monitor the impact of PDTAs on HF: adherence to medication and yearly number of echocardiograms. Data from 2021 show wide variation in these indicators, suggesting significant differences in quality of care across Italy. Adherence to HF medication ranges from approximately 70% in Sardinia to 2% in Valle d'Aosta, while the number of people with HF having an adequate number of echocardiograms is 36% in Friuli-Venezia Giulia versus a mere 7% in Lazio.³

Clinical databases, including those for the monitoring of HF, are already in place in some regions, and they have the potential to drive improvements in care. Certain regions, such as Emilia-Romagna, Lombardy and Veneto, have developed their own administrative (and sometimes also clinical) databases, using them to better tailor interventions by identifying and assessing target populations, high-risk groups and patient needs.⁶ Evidence shows that among the regions that use clinical databases, HF is one of the most closely monitored conditions.²⁰ Despite the benefits of the database for better care planning and standardised data collection, a 2018 survey highlighted that regional authorities may face challenges regarding privacy limitations on information, incomplete or low-quality data, obsolete coding systems and wide variability in analyses, even when they are performed within the same region.²⁰



Action: call on national and regional health authorities to harness data for improving the quality of care for people with HF

Advocates should call on national and regional authorities to ensure that the HF data that they and specialist registries such as ANMCO collect are used to inform better decision-making. To this end, advocates could encourage health authorities to:

- **use real-world data** collected for HF indicators and clinical databases to better understand gaps in care, such as lack of echocardiograms, and allocate resources more effectively
- **set up local data-sharing systems** to improve collaboration between healthcare professionals and allow them to gather instant feedback about the quality of care provision
- **standardise data collection and analysis** to improve the impact that this data collection can have on policymaking and service-planning.



Where has this approach succeeded?

An HF data collection project in the healthcare district of Bari that ran between 2018 and 2021 saw an increased adherence to guideline recommendations – in particular, the prescription of recommended medication after a hospitalisation for HF. The project involved a close interaction between hospitals and health district cardiologists. Patient data were shared through a web-based database, which collected demographic, clinical, laboratory and echocardiographic data.²¹

Circulation and implementation of heart failure care guidance

Existing guidelines have the potential to transform HF care, and PDTAs could provide a route to better implement guidelines on recommended care.

Evidence suggests that clinicians are determined to implement guidelines, but systemic barriers continue to impair care pathways. Clinical guidelines for HF are consensus documents intended to support clinical decision-making.²² A 2022 study involving 106 Italian cardiology sites reported high adherence to the European Society of Cardiology (ESC) guidelines for most indicators.²³ It also showed that reminders and educational meetings have the potential to further improve adherence.²³ Nonetheless, inefficiencies might still exist, with patients reporting long waiting times in the SSN in general, especially in the south.⁴ The use of biomarkers, such as natriuretic peptides, as tools for the diagnosis and monitoring of HF is generally still very low, and experts cite issues with reimbursement as a barrier.¹¹

PDTAs for HF aim to ensure the delivery of best-practice integrated care for HF across regions. National authorities recommended the development of clinical pathways for specific diseases as one of the PNC's main pillars.⁸ Although some cities, such as Trieste and Avezzano, had developed PDTAs for HF before the PNC recommended them,^{24 25} the systematic and widespread development of PDTAs for HF seems to have started with the implementation of this plan.



Action: call on regional health authorities to (further) develop PDTAs specific to HF and make patient empowerment part of these pathways

The PNC calls for specific clinical pathways to be developed for HF to improve care and decision-making. However, PDTAs may also help people with HF better navigate their care journey. To this end, advocates could ask regional authorities to:

- develop regional PDTAs for HF, if they do not exist already
- develop patient materials that make care pathways easy to understand and follow by explaining what role they can play in the care and support of people with HF
- identify inefficiencies in the care pathway, such as long waiting times,⁴ and address them by streamlining the pathways and using technology to help people with HF and healthcare professionals manage the condition
- **implement multi-faceted education programmes**, including electronic reminders and face-to-face sessions, to support not only HF specialists but also healthcare professionals outside of cardiology.



Where has this approach succeeded?

The project +Vita ASL Latina, developed in collaboration with GPs, aims to make the treatment pathway for people with chronic health conditions simpler and more efficient. It includes messaging systems to remind these individuals about forthcoming appointments.²⁶ The project has already implemented plans for diabetes and chronic obstructive pulmonary disease (COPD), with HF next in line.²⁶

Investment in the digital transformation of the health system

The National Recovery and Resilience Plan presents a major opportunity for the digital transformation of HF care.

The Italian government has committed to advancing the digitalisation of healthcare in Italy as part of its recovery plans. The post-COVID-19 National Recovery and Resilience Plan (Piano Nazionale di Ripresa e Resilienza, PNRR), which was rolled out in 2022, set out ambitious digital health objectives, including the digitalisation of the SSN and the introduction of telemedicine services at regional and local levels.²⁷ The PNRR also aims to reduce inequalities and increase the efficiency of services by enhancing regional healthcare networks and using digital innovations in healthcare.²⁸ The funding amounts to approximately €15 billion for health until 2026,²⁷ with €4 billion allocated to digitalising out-of-hospital care.²⁹

Coordinated roll-out at local level has been described as critical for the successful delivery of the plan. Regional steering committees ('cabina di regia') have been set up to execute the plan at the local level and pre-empt coordination issues. Experts have described the recovery plan as a key opportunity to improve HF care, but they have also warned that local health services would need to be well organised and integrated with hospital care to avoid disruptions and inefficiencies in the delivery of HF care pathways. 30

The use of telemedicine in the management of chronic conditions has increased due to the COVID-19 pandemic, but there is a need to extend its use in HF. In the first two years of the pandemic, several eHealth applications for managing chronic conditions were launched in different Italian regions.⁶ For instance, the Italian Association of Hospital Cardiologists developed the app CuorMio for people with cardiovascular disease, including HF. It allows them to set up medication reminders, review tests and store files to track treatments.³¹ However, a 2022 review reports that only one of the 39 reviewed studies on the use of telemedicine during the pandemic in Italy focused on HF.³² Furthermore, experts assert that Italy was generally unprepared to use telemedicine at the beginning of the pandemic,³² suggesting much remains to be done to enable its use for HF in daily clinical practice. At the time of writing this brief, the Istituto Superiore di Sanità (ISS) was finalising consensus documents on telecardiology, telemonitoring and telerehabilitation for cardiovascular disease, with a view to developing national guidelines.³³



Action: call on regional authorities to develop guidelines that set out clear standards for the provision and use of telemedicine services for HF to ensure access to high-quality care

HF advocates could:

- request that authorities develop standards for the provision and use of telemedicine
- ask regional health authorities to update PDTAs for HF to include telemedicine.



Where has this approach succeeded?

The region of Friuli-Venezia Giulia updated its PDTAs in 2020 to include the use of telemedicine in the care of people with HF. The guidance provides a detailed description of a classic structure for a telemedicine model and notes various health devices that can be used to monitor the condition.³⁴



Action: call on health authorities to leverage telemedicine to address inequalities in access to HF care and improve care standards

Referencing the PNC and the Pact for Health 2019–21, HF advocates could:

- request funding provided by the PNRR to facilitate the use of telemedicine as part of out-of-hospital care for HF²⁹
- work with research institutions in periodically evaluating the effectiveness of eHealth applications and remote monitoring to assist people with managing their HF
- make sure that the use of telemedicine is inclusive of various social and cultural backgrounds and levels of familiarity with the technology.

Where has this approach succeeded?

The 'Healing at home' project at Sant'Eugenio Hospital, Rome, which was launched in November 2021, aims to guarantee continuity of care through the use of telemonitoring and telenursing for older, frail patients after their discharge from the hospital. The specialist unit in the hospital sets up a care plan following discharge, and carers provide telemonitoring with the involvement of the GP.35

At the beginning of the pandemic, the Lazio region issued guidelines for setting the quality of care and standardising telemedicine services for people in need of regular contact with or particular assistance from healthcare professionals, including patients with chronic conditions. The comprehensive document provides detailed descriptions of the processes of setting up, conducting and following up on appointments. It also covers remote control of implantable devices, social services, privacy issues and pricing.³⁶

In October 2022, the Italian Association of Patients with Heart Failure (Associazione Italiana Scompensati Cardiaci, AISC) completed a pilot study with a telemonitoring station supervised by a nurse. Patients or their carers performed the daily measurements, which were sent via a smartphone to a central platform. This allowed an increase in early interventions, potentially reducing visits to the ER, and helped optimise treatment for HF. Despite high patient satisfaction overall, some patients and carers reported experiencing technical difficulties and increased anxiety.³⁷

During the first year of the pandemic, the Department of Translational Medicine, University of Naples Federico II, set up a telemedicine service to facilitate follow-up with people with HF. The system was based on the use of analogue phone calls to avoid exclusion due to social disparities, such as lack of access to smartphones. Over the course of a few weeks, the project saw better outcomes – reduced hospitalisation alongside the same mortality – compared with a similar period the year before.³⁸

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About the Heart Failure Policy Network

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