

The Value of Diagnostic Information in Heart Failure



DISCLAIMER

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Heart Failure – A common, serious condition affecting patients' quality of life, healthcare systems' sustainability and productivity



At least **15m** people live with HF across 51 countries.⁴

One in five can expect to live with HF at some point in her or his life.¹⁻³



Patients with advanced HF have a **lower quality of life** than patients with advanced cancer.^{2,8}

HF is also associated with severe **depression** and **anxiety**.¹³



Heart Failure is the **leading cause** of unplanned hospital re-admissions.⁶⁻⁷



Costs per patient are substantial: In Germany, a patient costs the HC system between **€14'297** and **€19'762**, depending on the frequency of physician visits.



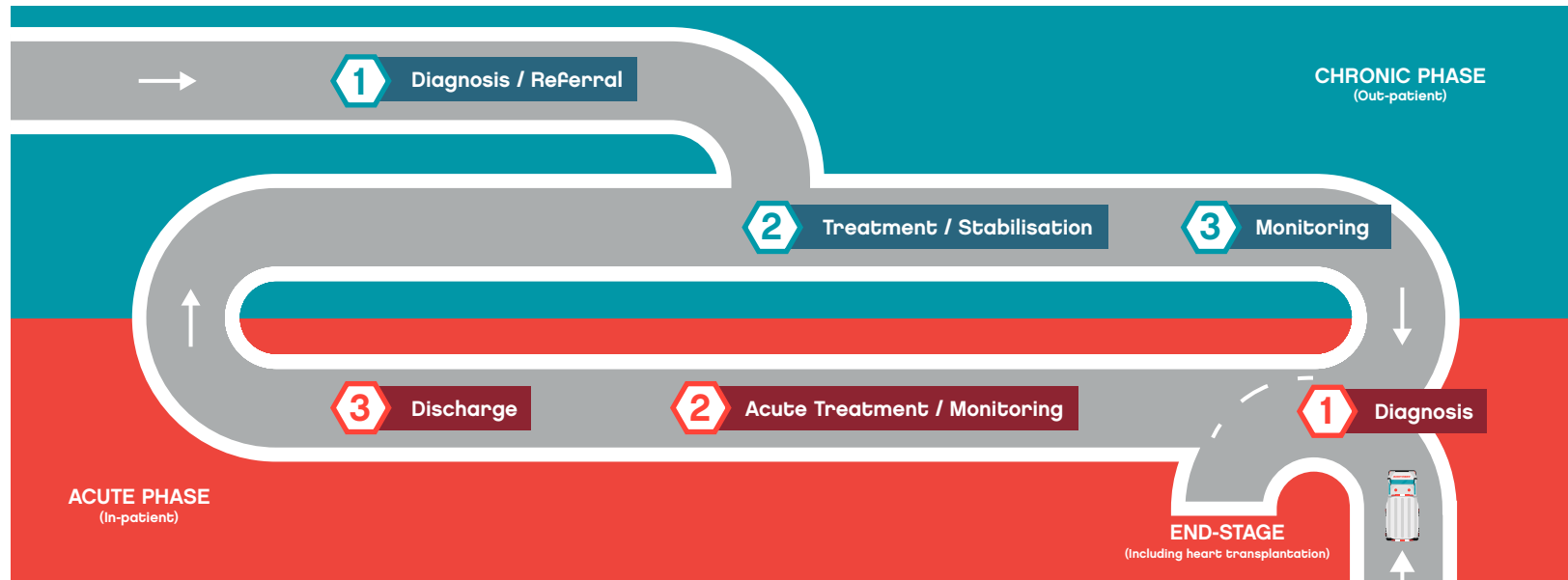
Heart Failure carries a severe **socio-economic burden**, negatively impacting the productivity of patients and carers.

The costs of informal care in Ireland amount to more than double of the direct medical cost of **€158m**.¹⁴

HF: Heart Failure
HC: Healthcare
Bn: Billion
m: Million

The Heart Failure patient pathway is complex as patients may experience both chronic and acute (requiring hospital admission) stages of the condition

Timely diagnosis, treatment and effective monitoring are crucial



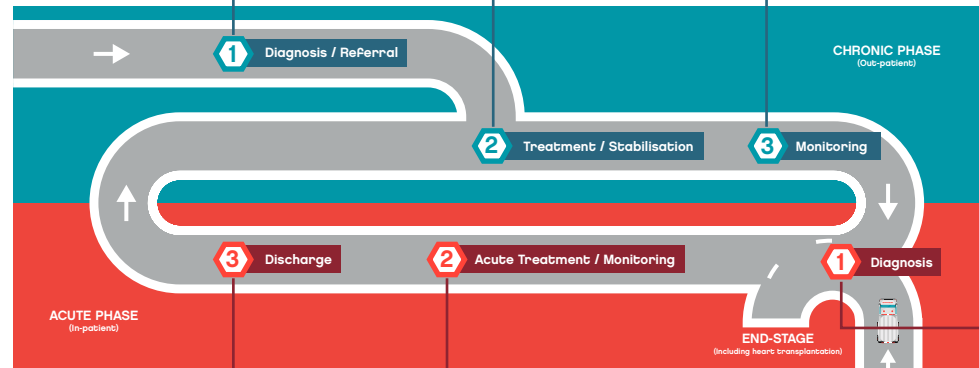
CHALLENGE

Untapped opportunities along the patient pathway lead to suboptimal Heart Failure care

- There are high rates of **misdiagnosis** as well as **missed diagnosis** as symptoms are not HF specific.¹⁸
- Echocardiographs are conducted and interpreted by specialists, which creates problems regarding the diagnostic capacity and consequently patients may be subject to substantial **waiting times** before seeing a specialist.^{17,29}
- In England, between 2010 and 2013 patients diagnosed with HF only 24% of patients with recorded HF symptoms followed a pathway aligned with **clinical guidelines**. A total of 44% of patients had neither an echocardiogram, nor a NT-proBNP test conducted.²⁴
- Patients are **referred too late to a specialist**. Existing estimates of delays from first presentation to diagnosis range from several months in Germany to up to one year in Ireland.^{26,28}

- Patients with chronic HF are typically **under-dosed**^{17,29}, with multiple therapies applied incrementally and suboptimal doses. According to a Swedish study, only 9% of patients received the combination at target dose in the primary care setting.⁷⁵

- Patients should be monitored to keep track of the HF disease process.³⁵ Critical for successful monitoring is the implementation of **HF care programs and integrated care** pathways, which is also recommended in the guidelines.^{1,36,37}
- The **lack of close monitoring** often leads to patient non-adherence to lifestyle advice or to their medication impacting real world outcomes.^{1,4}



- Patients leaving the hospital after acute HF episodes remain at **high risk of death** and **hospital re-admission** for up to 3 months.^{31,34}
- **Hospital discharge planning** and **close follow-up** with dedicated contact points are considered **best practice**.³⁰

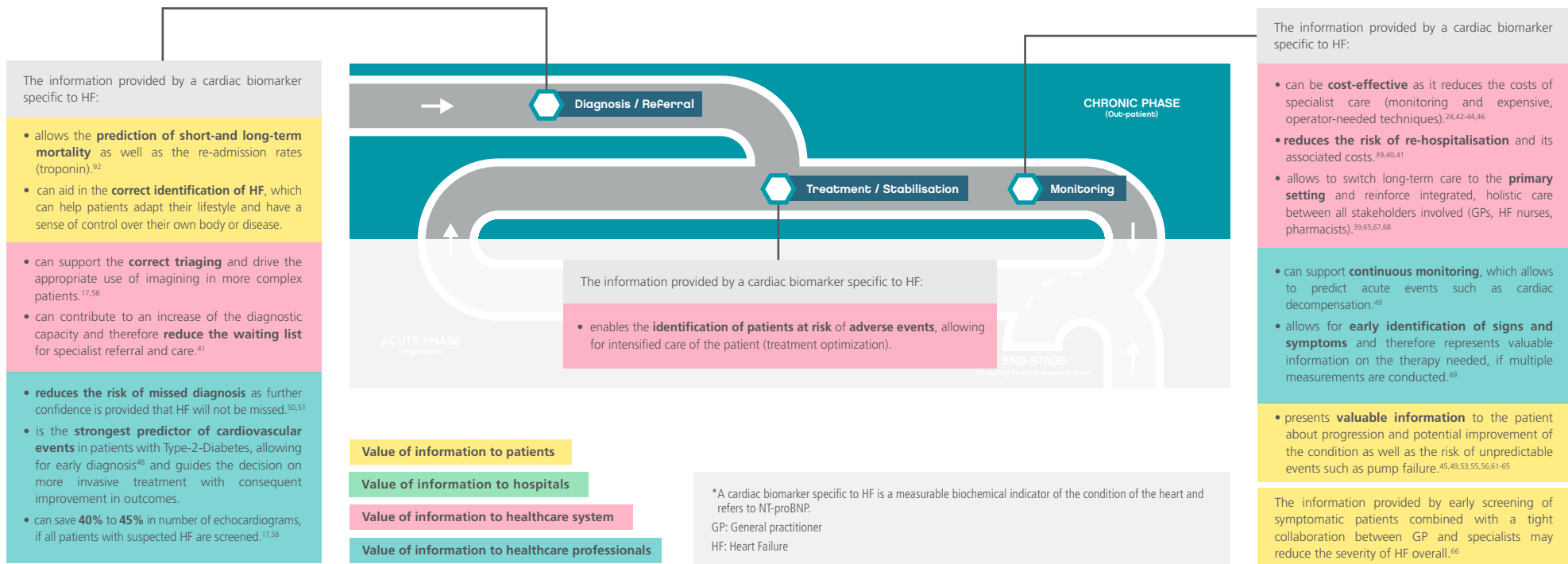
- Hospitalisation costs, room and boarding fees are the **greatest cost drivers** in HF, contributing to 43% of the in-patient costs.¹⁹

HF: Heart Failure
NT-proBNP: N-terminal pro-B-type natriuretic peptide
ED: emergency department.
POCT: Point of care testing

OPPORTUNITY

The use of information provided via cardiac biomarkers may address current shortcomings in Heart Failure* care

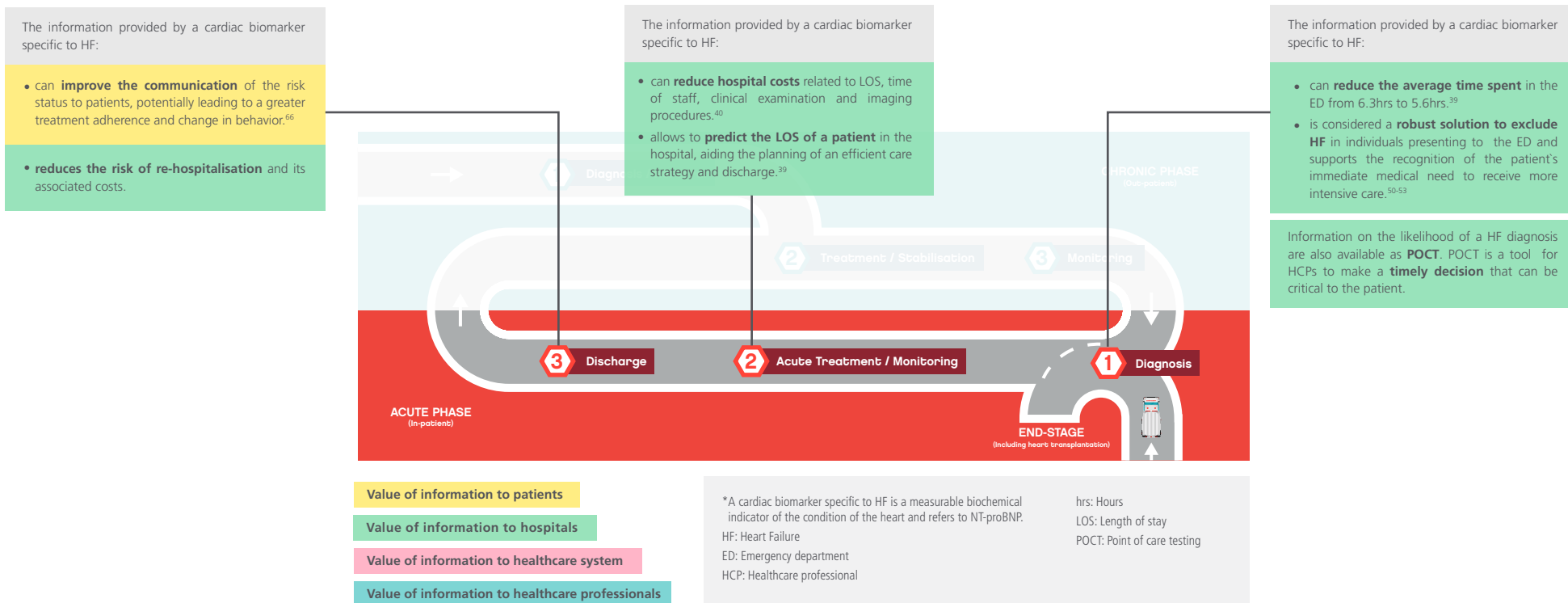
Value creation at each step of the patient pathway and to all stakeholders in the healthcare system



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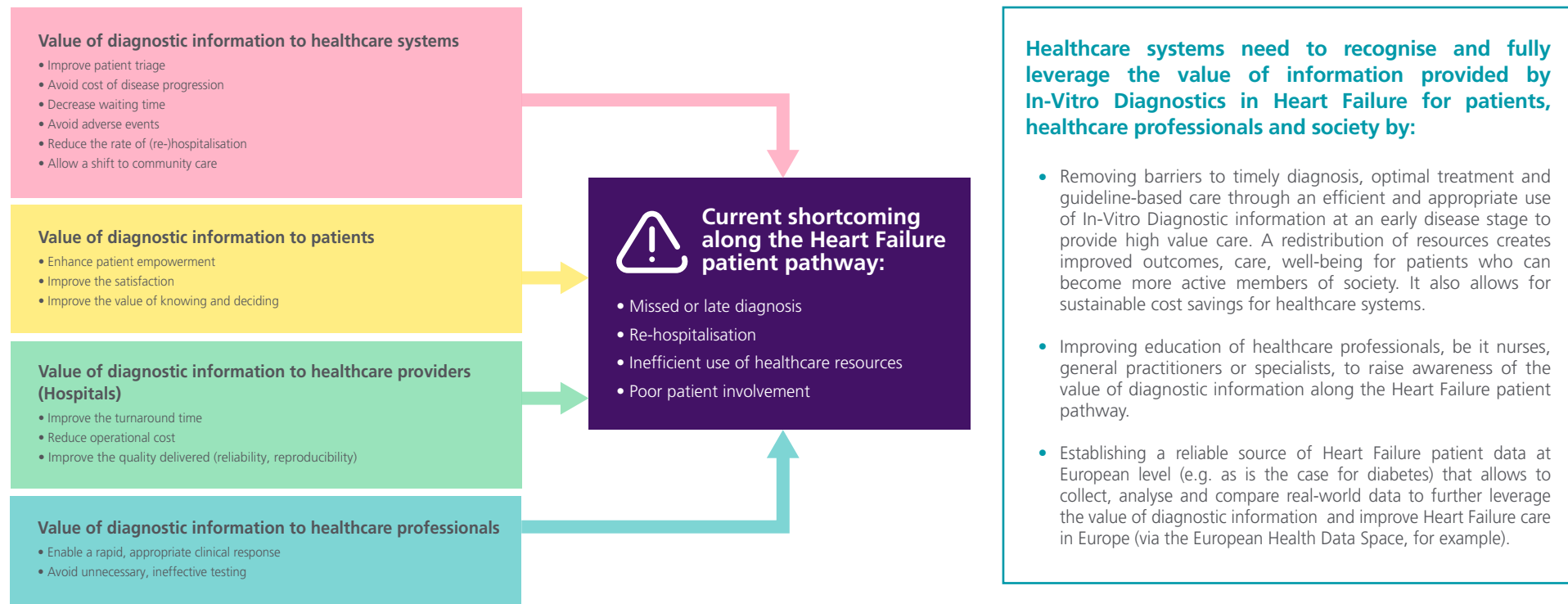
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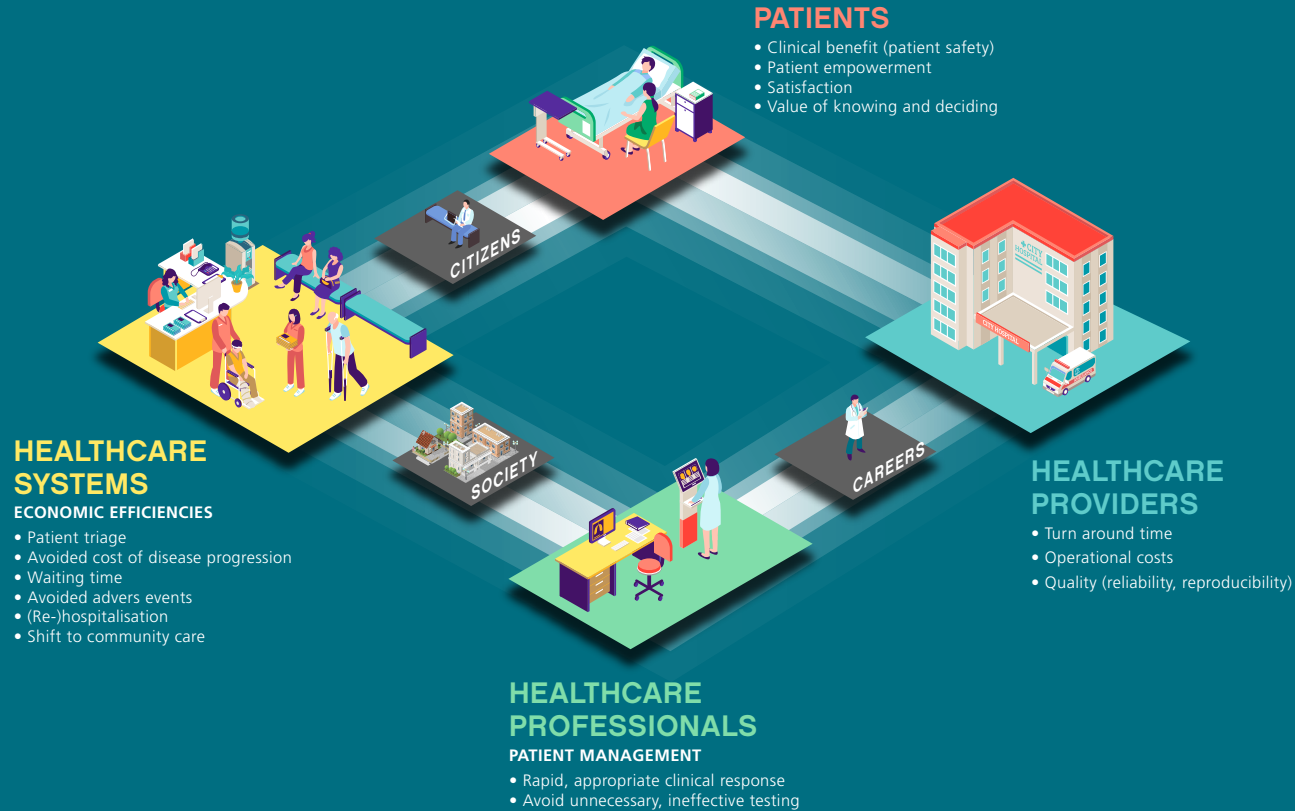
The information provided by In-Vitro Diagnostics such as cardiac biomarkers specific to Heart Failure* can be a valuable solution to the challenges in managing this disease

Diagnostic Information brings multidimensional value from healthcare pathway to health path¹²



*A cardiac biomarker specific to HF is a measurable biochemical indicator of the condition of the heart and refers to NT-proBNP.

The Value of Diagnostic Information



Information Boxes

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Heart failure describes the condition where the heart is not able to pump enough blood to meet the needs of the body.⁵ From a clinical perspective, patients have typical symptoms such as breathlessness, and signs such as elevated jugular venous pressure.⁹ HF that develops suddenly, with severe initial symptoms, is described as acute HF. HF that develops gradually over time is known as chronic HF.¹⁰ No system of diagnostic criteria has been agreed on as the gold standard for HF. Guidelines recommend measuring brain natriuretic peptide (BNP) followed by an ultrasound of the heart if positive. This is recommended in those with shortness of breath. In those with worsening HF, both a BNP and a troponin are recommended to help determine likely outcomes.

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An **echocardiography, echocardiogram, cardiac echo** or simply an **echo**, is an **ultrasound** of the heart. It is conducted by a trained specialist. Echocardiography uses standard two-dimensional, three-dimensional, and Doppler ultrasound to create images of the heart. Echocardiography has become routinely used in the diagnosis, management, and follow-up of patients with any suspected or known heart diseases. It is one of the most widely used diagnostic tests in cardiology. It can provide a wealth of helpful information, including the size and shape of the heart, pumping capacity, and the location and extent of any tissue damage. An echocardiogram can also give physicians other estimates of heart function, such as a calculation of the cardiac output, ejection fraction, and diastolic function (how well the heart relaxes).

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Point of Care Testing (POCT) is defined as medical diagnostic testing at or near the point of care — that is, at the time and place of patient care. This contrasts with the historical pattern in which testing was wholly or mostly confined to the medical laboratory, which entailed sending off specimens away from the point of care and then waiting hours or days to learn the results, during which time care must continue without the desired information.

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In-Vitro Diagnostic (IVD) tests are done on samples such as blood or tissue that have been taken from the human body.¹⁵ The principal intended purpose of an IVD is to provide information on one or more of the following medical purposes¹¹:

- Information concerning a physiological state e.g. menopause assay, ovulation assay, pregnancy test
- Information concerning a pathological state e.g. human immunodeficiency viruses assay
- Information concerning a congenital abnormality e.g. evaluation of the risk of trisomy¹⁶
- to determine the safety and compatibility with potential recipients e.g. determination of blood groups of the ABO system*
- to monitor therapeutic measures e.g. digitoxin assay

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