The Value of Diagnostic Information in Heart Failure

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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.5-7

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
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.
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-dosed13,25, 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.73
- Patients should be monitored to keep track of the HF disease process. Critical for successful monitoring is the implementation of HF care programs and integrated care pathways, which is also recommended in the guidelines.1,14,27
- The lack of close monitoring often leads to patient non-adherence to lifestyle advice or to their medication impacting real world outcomes.1
- In acute cases of HF, clinicians require a rapid response following a test. When presenting in ED, POCT has the potential to speed up the diagnosis.89
- Hospitalisation costs, room and boarding fees are the greatest cost drivers in HF, contributing to 43% of the in-patient costs.19
- 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

HF: Heart Failure
NT-proBNP: N-terminal pro-B-type natriuretic peptide
ED: emergency department
POCT: Point of care testing
### 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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<th>OPPORTUNITY</th>
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#### Value of information to patients
- Enables the identification of patients at risk of adverse events, allowing for intensified care of the patient (treatment optimization).
- Can support continuous monitoring, which allows to predict acute events such as cardiac decompensation.
- Allows for early identification of signs and symptoms and therefore represents valuable information on the therapy needed, if multiple measurements are conducted.
- Presents valuable information to the patient about progression and potential improvement of the condition as well as the risk of unpredictable events such as pump failure.

#### Value of information to hospitals
- Can be cost-effective as it reduces the costs of specialist care (monitoring and expensive, operator-needed techniques).
- Reduces the risk of re-hospitalisation and its associated costs.
- Allows to switch long-term care to the primary setting and reinforce integrated, holistic care between all stakeholders involved (GPs, HF nurses, pharmacists).

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### The information provided by cardiac biomarker specific to HF:
- Allows the prediction of short-and long-term mortality as well as the re-admission rates.
- Can aid in the correct identification of HF, which can help patients adapt their lifestyle and have a sense of control over their own body or disease.
- Can support the correct triaging and drive the appropriate use of imaging in more complex patients.
- Can contribute to an increase of the diagnostic capacity and therefore reduce the waiting list for specialist referral and care.
- Reduces the risk of missed diagnosis as further confidence is provided that HF will not be missed.
- Is the strongest predictor of cardiovascular events in patients with Type-2-Diabetes, allowing for early diagnosis and guides the decision on more invasive treatment with consequent improvement in outcomes.
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### *A cardiac biomarker specific to HF is a measurable biochemical indicator of the condition of the heart and refers to NT-proBNP.*

GP: General practitioner
HF: Heart Failure
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Value creation at each step of the patient pathway and to all stakeholders in the healthcare system

- Can improve the communication of the risk status to patients, potentially leading to a greater treatment adherence and change in behavior.
- Reduces the risk of re-hospitalisation and its associated costs.

The information provided by a cardiac biomarker specific to HF:
- Can reduce hospital costs related to LOS, time of staff, clinical examination and imaging procedures.
- Allows to predict the LOS of a patient in the hospital, aiding the planning of an efficient care strategy and discharge.

Information on the likelihood of a HF diagnosis are also available as POCT. POCT is a tool for HCPs to make a timely decision that can be critical to the patient.

*A cardiac biomarker specific to HF is a measurable biochemical indicator of the condition of the heart and refers to NT-proBNP.
HF: Heart Failure
ED: Emergency department
HCP: Healthcare professional

Hrs: Hours
LOS: Length of stay
POCT: Point of care testing
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

- **Value of diagnostic information to healthcare systems**
  - Improve patient triage
  - Avoid cost of disease progression
  - Decrease waiting time
  - Avoid adverse events
  - Reduce the rate of re-hospitalisation
  - Allow a shift to community care

- **Value of diagnostic information to patients**
  - Enhance patient empowerment
  - Improve the satisfaction
  - Improve the value of knowing and deciding

- **Value of diagnostic information to healthcare providers (Hospitals)**
  - Improve the turnaround time
  - Reduce operational cost
  - Improve the quality delivered (reliability, reproducibility)

- **Value of diagnostic information to healthcare professionals**
  - Enable a rapid, appropriate clinical response
  - Avoid unnecessary, ineffective testing

Healthcare systems need to recognise and fully leverage the value of information provided by In-Vitro Diagnostics in Heart Failure for patients, healthcare professionals and society by:

- Removing barriers to timely diagnosis, optimal treatment and guideline-based care through an efficient and appropriate use of In-Vitro Diagnostic information at an early disease stage to provide high value care. A redistribution of resources creates improved outcomes, care, well-being for patients who can become more active members of society. It also allows for sustainable cost savings for healthcare systems.

- Improving education of healthcare professionals, be it nurses, general practitioners or specialists, to raise awareness of the value of diagnostic information along the Heart Failure patient pathway.

- Establishing a reliable source of Heart Failure patient data at European level (e.g. as is the case for diabetes) that allows to collect, analyse and compare real-world data to further leverage the value of diagnostic information and improve Heart Failure care in Europe (via the European Health Data Space, for example).

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The Value of Diagnostic Information

**HEALTHCARE SYSTEMS**
- **Economic Efficiencies**
  - Patient triage
  - Avoided cost of disease progression
  - Waiting time
  - Avoided adverse events
  - (Re-)hospitalisation
  - Shift to community care

**PATIENTS**
- Clinical benefit (patient safety)
- Patient empowerment
- Satisfaction
- Value of knowing and deciding

**HEALTHCARE PROVIDERS**
- Turn around time
- Operational costs
- Quality (reliability, reproducibility)

**HEALTHCARE PROFESSIONALS**
- Rapid, appropriate clinical response
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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. From a clinical perspective, patients have typical symptoms such as breathlessness, and signs such as elevated jugular venous pressure. HF that develops suddenly, with severe initial symptoms, is described as acute HF. HF that develops gradually over time is known as chronic HF.

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.

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).

**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.

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

- 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 trisomy
- 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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