

# A virtual panel discussion

*The value of diagnostic information (VODI) in heart failure.* 





On 16 November 2020, Roche Diagnostics hosted 'The value of diagnostic information (VODI) in heart failure', a virtual panel discussion featuring six experts representing a range of stakeholders from across Europe. The discussion centred on how diagnostic information could be used to guide more effective and efficient healthcare delivery, with a specific focus on heart failure (HF).





### Key take-home messages included:

- The VODI framework outlines how to define and measure the value of outcomes created by in vitro diagnostics (IVDs) and how to incorporate this information into decision-making processes.
- Therapeutic value can be measured in terms of direct clinical benefit, whereas the value generated by IVDs derives from the information obtained from the test the value of diagnostic information.
- In the case of HF, appropriate use of N-terminal pro-brain natriuretic peptide (NT proBNP) testing can support timely diagnosis and person-centred management of the syndrome, thereby improving outcomes, reducing hospitalisations and protecting healthcare resources.
- For people living with HF, access to diagnostic information can enhance patient empowerment and improve satisfaction with care.
- IVDs have been essential for the adaptation of HF care during the COVID-19 pandemic, demonstrating their wider value in new care models such as remote monitoring and telemedicine.

The panel recommended ways to recognise, measure and fully leverage the benefits of diagnostic information for people living with HF, health systems and society. These were:

- Educating healthcare professionals, including nurses, general practitioners (GPs) and specialists, on the value of diagnostic information along the HF care pathway.
- Reimbursing NT-proBNP testing universally across care settings and incentivising its appropriate use to support the timely diagnosis and optimal management of HF.
- Investing in information technology (IT) systems to collect and share real-world data, which currently sit in silos, to demonstrate the value of diagnostic information in HF care.

## Heart failure: the burden on people who live with it, healthcare systems and society

HF is a common and complex syndrome where the heart becomes too weak or stiff to pump enough blood to the body. One in five people can expect to be diagnosed with HF at some point in their lives and the syndrome places a considerable burden on people living with HF, their families/ carers, healthcare systems and society. Symptoms of HF, such as breathlessness and extreme fatigue, can limit a person's ability to work, travel and socialise, potentially reducing their quality of life. HF is also a major driver of healthcare costs – it causes almost two million hospital admissions in Europe every year and is the most common cause of hospital admissions in people over the age of 65.

Much can be done to alleviate the burden of HF in Europe, but the implementation of effective prevention and management models is often limited. The field of HF needs 'game-changers' to promote efficiency and value in care while improving the sustainability and resilience of our healthcare systems. While the COVID-19 pandemic will continue to require political attention, governments must remember that HF will persist as a major source of avoidable hospital admissions long after COVID-19 has been contained. Now, more than ever, we must think about how healthcare systems can become more resilient and better prepared for future crises that threaten the delivery of healthcare, including care for people living with HF.

# Expert presentations



**Ms Sophie Marie Meiser** Manager of Market Access and Economic Policies, MedTech Europe

I VDs were an essential component of healthcare systems' response to the COVID-19 outbreak. They will continue to have a vital role in the future by driving clinical decisionmaking and supporting the sustainability of healthcare systems. In the case of HF, diagnostic information is essential for an accurate and timely diagnosis, which improves patient outcomes and reduces the pressures on healthcare providers. Whereas therapeutic value can be measured as the direct clinical benefit for the patient, this is not the case for diagnostics, despite their importance to clinical decisionmaking. The value generated by IVDs is therefore derived from the information obtained from the test – the value of diagnostic information – which is more difficult to quantify.

#### "Diagnostic information is power – power to deliver value for the individual patient, but also for society."

This is a challenge we must embrace if we are to truly realise the benefits of diagnostics and their contribution to longerterm sustainability in response to population ageing, the increasing prevalence of chronic conditions and, more recently, the COVID-19 pandemic. MedTech Europe has collaborated with a group of experts to develop the VODI framework, outlined in further detail below.



**Dr Bernarda Zamora** Senior Economist, Office of Health Economics,

Value-based healthcare aims to deliver the best outcomes to patients relative to cost. For this concept to become a reality, we need institutional and policy structures capable of aligning the views and interests of different stakeholders, including governments, insurers, healthcare providers and professionals, researchers and patients. We must collect realworld data on patient outcomes and costs in clinical practice, laboratories, hospitals and primary care. If better outcomes are achieved via lower costs, then this saving must be recognised. Multidisciplinary and integrated person-centred care must be supported by adequate IT systems and outcomebased incentivisation should be introduced to support effective care delivery.

### "The results of in vitro testing influence as many as 70% of clinical decisions."

The VODI framework outlines how to define and measure the value of outcomes created by IVDs, and how to incorporate this information into decision-making processes. It aims to identify the multi-faceted value of IVDs to relevant stakeholders (see **Figure 1, opposite page**).

In the case of HF, use of NT-proBNP testing is a good example of a specific diagnostic intervention that could bring several benefits, including:

- Timely diagnosis of HF in primary care, which can save downstream costs and reduce waiting lists for echocardiography
- Efficient and accurate triaging of people admitted to acute care
- Tailored management and medication optimisation, resulting in better outcomes for people living with HF
- Consistent monitoring of HF severity as an indicator for risk of hospitalisation and mortality
- A 35% reduction in hospital readmissions, a 40-minute reduction in emergency department waiting times and a 15% decrease in direct medical costs.

### **VODI:** Value of Diagnostic Information



Figure 1: The VODI framework



#### Ms Carys Barton

Heart Failure Nurse Consultant, Imperial College Healthcare NHS Trust, UK; Chair, British Society for Heart Failure Nurse Forum

Better use of NT-proBNP testing in primary care can support timely diagnosis of HF and initiation of guidelinerecommended therapies, thereby reducing the risk of hospitalisation. Approximately 80% of people living with HF are diagnosed in hospital, despite 40% displaying symptoms that should have triggered earlier investigations. This places a considerable strain on hospitals, particularly in light of the COVID-19 pandemic.

## "NT-proBNP testing is simple, minimally invasive, cost-effective and cost saving."

Diagnostic information also has a role in the treatment and management of HF. For example, NT-proBNP testing can help determine whether a person living with HF needs an escalation in medication or further intervention, or additional care for their comorbidities. NT-proBNP testing can guide efficient use of healthcare resources. A good example is its role in ruling out HF and reducing the burden on echocardiography services, which are stretched thin due to a national shortage of cardiac scientists able to conduct this test. At the Imperial College Healthcare NHS Trust, NT-proBNP testing had a crucial role in determining which patients urgently needed face-to-face consultations during the COVID 19 pandemic.



**Professor Damien Gruson** Head of Lab, Cliniques universitaires Saint-Luc, Belgium; Member of the European Commission's Expert Panel on Effective Ways of Investing in Health

Laboratory tests assist healthcare professionals in diagnosing HF. In addition to NT-proBNP, guidelines recommend a panel of tests to assess the status of people living with HF. For example, biomarkers such as troponin and haemoglobin can be used to characterise a person's HF, which supports the delivery of personalised HF care and treatment.

### 'Laboratory tests not only help to diagnose people with heart failure, but also help to profile patients for the appropriate use of hospital services."

The creation of new laboratory testing services in primary care can support the timely diagnosis of HF. During the COVID-19 pandemic, measurement of biomarkers using point-of-care devices enabled real-time monitoring of the health of people living with HF. The development of innovative sensors, similar to those in diabetes, will support the continuous monitoring of biomarkers in HF. This information, coupled with clinical data, can improve diagnosis and enhance precision care, leading to improvements in cardiovascular health and substantial cost savings.



**Mr Nick Hartshorne-Evans** Founder and Chief Executive of Pumping Marvellous Foundation, UK

Delayed diagnosis or misdiagnosis of HF has a detrimental impact on the psychological wellbeing and quality of life of people first experiencing symptoms of HF. It may also affect a person's ability to work. People living with HF have reported increased levels of stress, anxiety and depression due to delays in their diagnostic process. The timely diagnosis of HF has the power to impact millions of lives and there is a considerable need to increase awareness of signs and symptoms of HF among the public and healthcare professionals.

# "Diagnostics are the route 101 or first step to winning at heart failure."

NT-proBNP testing is essential for an efficient diagnosis, which ensures timely access to treatment and specialist-led support, and reduces the risk of costly hospital admissions. Levels of NT-proBNP could also be measured as part of routine blood tests at a one-stop HF clinic, enabling healthcare professionals to monitor the syndrome and optimise guideline-recommended medications accordingly.



### Professor Dr Yigal M Pinto

Head of Department of Experimental Cardiology, Deputy Head of Department of Clinical Cardiology; Scientific Director of the Heart Centre at the Academic Medical Centre, the Netherlands

Management of HF improves with better diagnostic information. But an essential question remains: which diagnostics are most valuable in the field of HF? HF is a syndrome and not a disease, which makes it more difficult to measure. In addition, the number and complexity of treatment options for HF has grown, amplifying the need for diagnostic parameters to guide clinical decision-making. While new treatments have demonstrated considerable survival benefits in clinical trials, it is much more difficult to determine treatment benefit in real-world settings. This may result in overtreatment – for example, 85% of implantable cardioverter-defibrillators given to people living with HF will never intervene.

### "What has made natriuretic peptides and specifically NT-proBNP stand out in recent years is that they provide an objective tool to measure one of the cornerstones of the pathophysiology of heart failure."

Diagnostic information could potentially help tailor treatments to the needs of each person living with HF, thereby improving outcomes while also reducing the costs associated with overtreatment. Measurement of natriuretic peptide (NP) levels enables consistent monitoring of wall stress caused by increased filling pressures in the heart, whereas echocardiography focuses solely on ejection fraction.



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#### Moderator

Following the presentations, **Mr Ed Harding**, Network Director of the Heart Failure Policy Network, moderated a panel discussion, taking into consideration questions raised by attendees.



# Panel discussion

### What is required to capture the value of diagnostic information in a structured and consistent way?

 Ms Meiser: The value assessment for diagnostics needs to be comprehensive, and it should include a sufficient time frame to capture outcomes and total costs during the expected healthcare pathway. It requires different methodological approaches to measure the perspectives of relevant stakeholders (patients, healthcare professionals, healthcare providers and healthcare systems) – we must go beyond traditional clinical and health economic domains, for example by using patient satisfaction surveys, long-term benefit simulation modelling and electronic health records. A key step in harnessing the value of diagnostic information and delivering value-based healthcare is to advance the interoperability of IT systems and real-world data, which currently sit in silos.

### How do we measure patient-reported outcomes, and what are the challenges in implementation?

 Dr Zamora: Patient-reported outcomes for HF and cardiovascular disease increasingly incorporate functional and psychosocial factors as well as the burden on families and carers. This has increased the complexity of these measures, making cross-country comparisons more difficult. Nonetheless, tools such as the patient-reported outcome measurement information system (PROMIS\*) are essential in the delivery of person-centred, value-based healthcare.

# How can we use patient-reported outcomes and diagnostic information to improve the lives of people with HF?

Mr Hartshorne-Evans: Quality of life data are rarely collected outside of clinical trials and research studies, meaning that policy change relies on data that may not be representative of the realities of living with HF. Quality of life is incredibly important for people living with HF, so we need to find a way to collect real-world data and incorporate this information into the stakeholder conversation. Diagnostic information, specifically NT-proBNP testing, is essential in empowering people in the diagnosis and management of HF.

# Which hurdles do you encounter in capturing the value of diagnostic information?

• **Professor Pinto:** There are three main barriers to the use of IVDs in HF. Firstly, the lack of awareness of NT-proBNP testing among healthcare professionals hinders the use of this test in practice. Secondly, healthcare professionals may not know how to interpret and use the results of an NT-proBNP test in the diagnosis and management of HF. Thirdly, restrictive reimbursement schemes may penalise, rather than incentivise, the use of diagnostics.

### How do we incentivise the use of diagnostics in HF?

- **Professor Gruson:** As we strive for integrated care, we must also move towards an integrated financing model. For example, we must be able to demonstrate the value of a diagnostic test introduced in primary care for the rest of the care pathway. Bundling IVDs into a package of services and improving the patient (consumer) experience of IVDs may also incentivise their use in practice.
- Ms Barton: The Quality Outcomes Framework (QOF) is a voluntary scheme in England that financially incentivises GPs for adhering to guideline recommendations in the diagnosis and management of HF, including use of NTproBNP testing. However, we need further education and training in HF for healthcare professionals to maximise the impact of this scheme.
- **Dr Zamora:** There is a need to generate evidence on the clinical utility of IVDs in real-world settings. Realistic expectations should be set around the standards for evidence, and surrogate clinical endpoints (e.g. readmissions) can be used to determine the value of NT-proBNP testing.
- **Mr Harding:** The Heart Failure Policy Network recently launched a landmark report entitled Heart failure policy and practice in Europe, which identifies varying reimbursement policies for NP testing across care settings in Europe, leading to differences in the use of this test.

### Can we use NT-proBNP as a surrogate endpoint for safety or efficacy in clinical trials in HF?

• **Professor Pinto:** Monitoring changes in NT-proBNP levels can be useful in some clinical trials, if done with caution. For example, changes in NP levels may be indicative of the likelihood of treatment benefit for outcomes such as hospitalisation and worsening HF. However, an important caveat is that NT-proBNP does not correlate well with arrhythmic outcomes.

#### Can we use NT-proBNP as a surrogate endpoint for safety or efficacy in clinical practice, for example in existing centres of excellence?

 Ms Barton: In clinical practice, NT-proBNP could be coupled with other measures such as New York Heart Association (NYHA) class or patient-reported outcome measures. During the COVID-19 pandemic, HF specialists have turned to remote monitoring for people with implantable cardiac devices. By combining the results of NTproBNP testing done in primary care with what we know about a person's symptoms, we get a detailed overview of their clinical status while minimising their risk of infection.

# What should we do with diagnostic information in HF when no effective treatment is available (e.g. in HF with preserved ejection fraction, HFpEF)?

- **Professor Pinto:** Clinical trials in HFpEF have not shown a mortality benefit, but this does not mean that there is no optimal treatment. In my practice, I use NT-proBNP testing more often in people with HFpEF, as it correlates directly with blood pressure and filling status of the heart and consequently with symptoms of HF. Echocardiography is far more complicated and less useful in people living with HFpEF.
- Professor Gruson: Investigation of the pathways leading to elevated NP levels could help identify new therapeutic targets, which may result in novel treatments for HFpEF.

### How would you communicate the value of diagnostic information in HF to a decision maker?

- Mr Hartshorne-Evans: The timely diagnosis of HF supports the mental health, wellbeing and quality of life of the person living the syndrome, which has downstream effects on how they participate in society. Diagnostic information, specifically NT proBNP testing, paired with other measures such as patient-reported outcomes, builds a detailed picture of what each person needs along the HF care pathway, thereby supporting person-centred integrated HF care and reducing the risk of costly hospitalisations.
- Ms Meiser: Harnessing the value of diagnostic information can increase the sustainability and resilience of healthcare systems, while also improving healthcare delivery and patient outcomes. This is more important than ever, given the demands on our healthcare systems today.
- **Professor Pinto:** We need accurate, quick and accessible diagnostics to manage HF. NT-proBNP testing offers this opportunity. Solely relying on echocardiography to manage HF is like relying on X-rays to manage COVID-19.
- Dr Zamora: We must put in place institutional arrangements to recognise value beyond cost-based reimbursement of diagnostics. Public funding should be used to support evidence generation in clinical practice, to ensure that the burden of demonstrating value does not fall solely on manufacturers.
- Ms Barton: Better community-based management of HF will deliver substantial socioeconomic and health-economic benefits: people who are well can contribute to society; unwell people are unable to do so. Harnessing the power of diagnostic information means that we will be able to get the right care to the right people at the right time, thereby reducing the risk of costly hospital admissions.
- Professor Gruson: The COVID-19 pandemic has demonstrated the value of diagnostics in protecting our citizens. In HF, we must prevent hospital admissions and worse outcomes, meaning that we must 'test, test, test'.

# Summary of key points

Speaker	What is the value of diagnostic information?	Endpoints: measuring the value of diagnostic information
Ms Sophie Marie Meiser	Better use of diagnostic information can increase the sustainability and resilience of healthcare systems while improving patient outcomes.	Measure the perspectives of all relevant stakeholders e.g. patients, healthcare professionals, healthcare providers and healthcare systems.
Dr Bernarda Zamora	Diagnostic information is an enabler of value-based healthcare – it supports the delivery of the best outcomes for patients relative to cost.	HF patients: survival, quality of life, disease severity, cost impact on patients/families. Healthcare systems/payers: economic (e.g. hospital readmissions, emergency waiting times), care delivery (e.g. hospital resource overuse, medical errors/adverse events), public health/societal benefits (e.g. increased community and home care, labour force participation).
Mr Nick Hartshorne-Evans	Diagnostic information can support the efficient diagnosis and management of HF, thereby improving the quality of life for people living with the syndrome.	Patient-reported outcomes measured in real-world settings (e.g. quality of life, psychosocial burden), diagnostic delays, unplanned hospital admissions, adherence to guideline-recommended therapies.
Professor Dr Yigal M Pinto	Diagnostic information can guide healthcare professionals in the management of HF, including the selection and optimisation of complex treatment choices.	Treatment costs and NT-proBNP-corrected endpoints e.g. survival and hospital admission rate.
Ms Carys Barton	Diagnostic information can support the timely diagnosis of HF, assist in the efficient and accurate triaging of people with HF and guide efficient use of healthcare resources.	Hospital admissions, access to HF specialists and guideline-recommended therapies, quality of life, morbidity and mortality.
Professor Damien Gruson	Diagnostic information enables researchers to better advise healthcare providers on best-practice HF management models that improve patient care as well as clinical and economic outcomes.	Clinical performance outcomes (e.g. length of stay), behavioural outcomes (e.g. patient satisfaction), economical outcomes (e.g. cost of management) and environmental outcomes (e.g. waste and energy)

# Further resources

- 1 The value of diagnostic information in personalised healthcare: a comprehensive concept to facilitate bringing this technology into healthcare systems
- 2 Heart failure: the hidden costs of late diagnosisPatient video: Dan's heart failure diagnosis
- **3** Economic incentives for evidence generation: promoting an efficient path to personalized medicine
- 4 Heart failure policy and practice in Europe

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