

LumiraDx participates in the Healthy Heart Bus Initiative with innovative, fingerstick blood NT-proBNP test

Background

Heart failure is not a single pathological diagnosis, but a clinical syndrome consisting of symptoms such as breathlessness and ankle swelling accompanied by signs of elevated jugular venous pressure and pulmonary crackles. In the UK, in 2023, there are estimated to be nearly 1 million people living with heart failure and 200,000 more diagnosed each year¹. However, it is those who are living with unidentified heart failure that should not be forgotten - which is thought to be nearly 340,000 people². The delayed presentation of these people, may mean they miss out on life-prolonging and symptom-improving medication.

Purpose

Across 2 days in February 2023, LumiraDx participated in a community-based initiative to improve knowledge of heart health and encourage people to #starttalkingaboutyourheart.

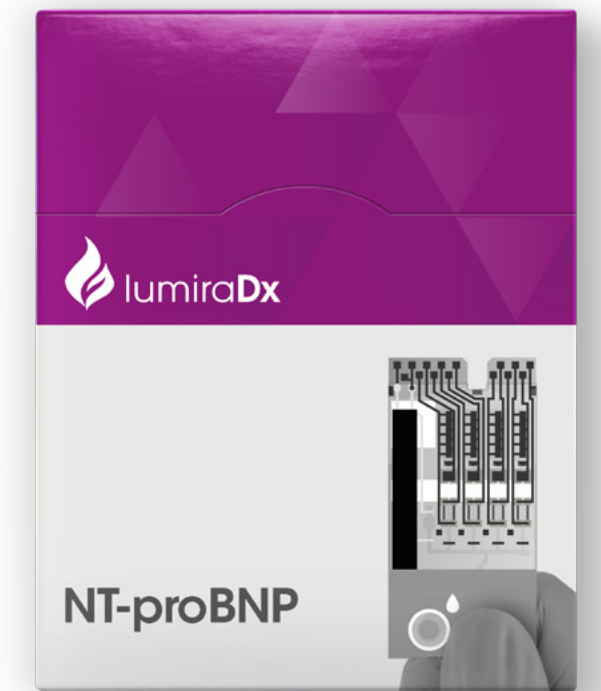
The collaboration was between several community-based heart health and heart failure charities, providers of health services and commercial organisations who all came together to drive awareness in heart health and potential ways to improve current pathways. This was an ideal opportunity for LumiraDx to explore how our innovative, direct fingerstick point of care NT-proBNP test, when used in a community setting, can assist in identifying this missing cohort of unidentified/undiagnosed people. This is the first step in understanding where change in current pathways can bring benefits that support both patients, and healthcare professionals to transform community-based healthcare.



Methods

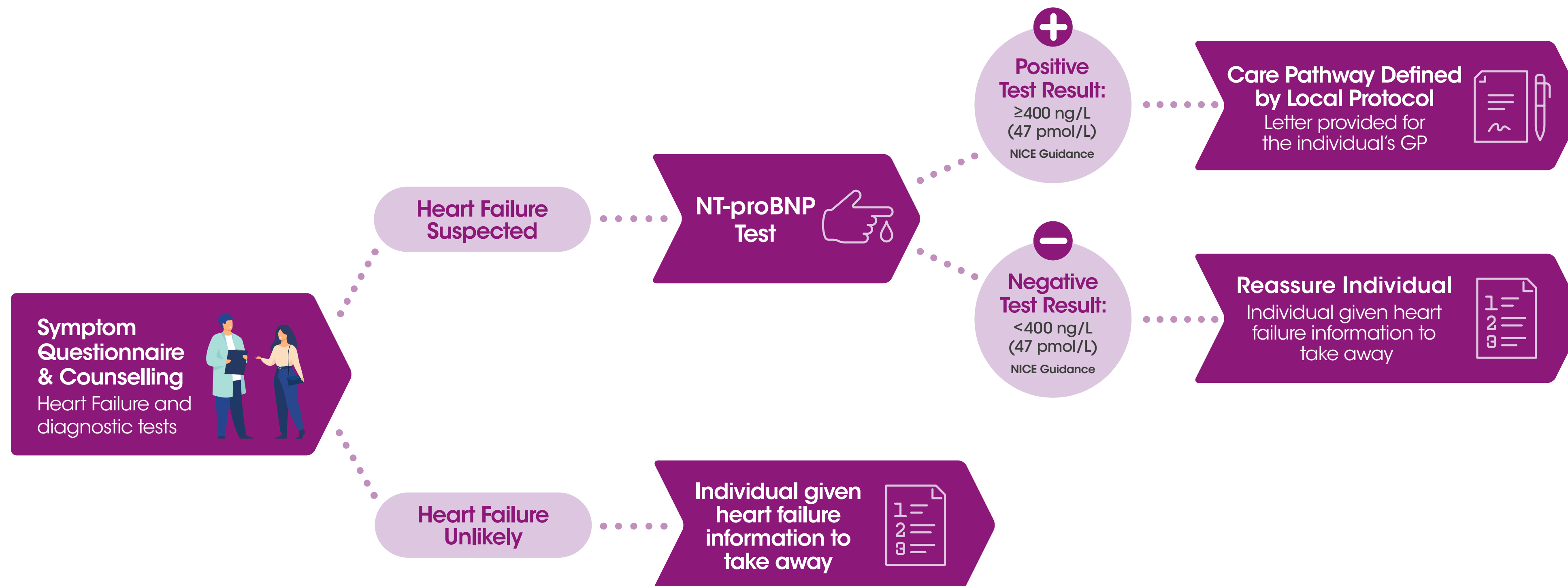
The community testing service was advertised across social media in the days preceding the walk-in clinic to increase awareness in the local surrounding area of the presence of the Community Heart Health Check service. Members of the public were able to access the Heart Health service in a centrally located community space, where healthcare professionals (HCPs) and members of the heart charities were on hand to provide information and support. People who attended the service were offered advice on heart health, there was an opportunity to have a heart rhythm check, and a stethoscope check (heart auscultation) which can detect heart valve disease. A questionnaire, designed by Heart Valve Voice (www.heartvalvevoice.com) was used to ascertain which people would benefit from a fingerstick NT-proBNP test, by asking questions around the signs and symptoms usually associated with heart conditions like heart failure.

The answers given to the questionnaire were reviewed by the HCP and the heart auscultation and pulse check were completed. The HCP then identified if an NT-proBNP test was required by ticking a box on the questionnaire form and adding any necessary comments.



- **Negative Symptom Questionnaire:**
Member of the public underwent auscultation and was provided with heart health awareness information.
- **Positive Symptom Questionnaire:**
 - Member of public was given a letter to take to their General Practitioner (GP) and any additional support or further information was provided by a member of the Heart Valve Voice team or Specialist nurse who was present.
 - Member of the public then took the completed questionnaire to the LumiraDx NT-proBNP test station. The 12 minute, fingerstick blood test was completed by HCP and then information on heart failure and counselling was given. The member of public was given a letter to take to their GP explaining the test that had been performed and the result.

Individual presents at community heart health-check service



“The Healthy Heart Bus is a great initiative to support the identification of possible heart problems in the community. With so many people suffering from unidentified heart failure in the community, and therefore not receiving appropriate management, the use of the LumiraDx NT-proBNP finger prick point of care test would seem to be a vital tool for any similar project”

Dr Matt Fay, GPwSI
Cardiovascular disease,
Westcliffe Health
Innovations Cardiology
Service

Fig. 1. Pathway followed in the Healthy Heart Bus Initiative

The NT-proBNP test

Those members of the public who were identified as positive for signs and symptoms of potential heart failure, had an NT-proBNP test performed by a HCP using the LumiraDx direct fingerstick NT-proBNP test³. The cut-off used for NT-proBNP was 400pg/mL (ng/L)* as outlined in the Westcliffe Cardiology Services: Managing of Heart Failure: detection and diagnosis (April 2021).

NT-proBNP test 400-2000pg/mL 6 week echo referral	NT-proBNP test ≥ 2001 pg/mL 2 week Urgent echo referral
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Fig.2. Cut-off for NT-proBNP adapted from Westcliffe Cardiology Services (April 2021)

Results

Day 1 of the service provision, 85 people attended the bus at Site 1, and, following a positive symptom questionnaire, 37 of those went on to have their NT-proBNP measured by direct fingerstick using the LumiraDx NT-proBNP test. 4 of the 37 people had an NT-proBNP result that was >400 pg/mL (ng/L).

On Day 2, 181 people attended the bus at Site 2 and 60 went on to have an NT-proBNP test, with 2 people having a result >400 pg/mL (ng/L).

In total, 266 people engaged with the Heart Health Community service over the 2 days, 97 of those went on to have their NT-proBNP measured using the LumiraDx NT-proBNP fingerstick test, with 6 of those being above the 400pg/mL (ng/L) cut-off outlined in Westcliffe Cardiology Services (Fig. 2). All 6 people were signposted to further investigation, and the member of the public with NT-proBNP >2001 pg/mL (ng/L) was fast tracked to the Heart Failure clinic.

Site 1	NT-proBNP pg/mL (ng/L)	Site 2	NT-proBNP pg/mL (ng/L)
Person 1	416	Person 1	437
Person 2	438.4	Person 2	656.8
Person 3	1299		
Person 4	3759		

Table 1: Summary of results, by site, that were above the established cut-off 400pg/mL (ng/L)

Conclusion

The aim of the Healthy Heart Bus Initiative is to raise public awareness of a range of potential heart conditions, and to also provide education. The opportunity for LumiraDx to join this worthwhile initiative fits entirely with the vision of transforming healthcare, and our direct fingerstick NT-proBNP test opens up this possibility. The bus empowered members of the public to seek advice, who perhaps were having difficulty in accessing healthcare professionals via their primary care services, or did not realise that the symptoms they were experiencing warranted further investigation.

For this initiative, the 400pg/mL (ng/L) cut-off for NT-proBNP was applied according to local guidelines. The European Society of Cardiology (ESC) clinical practice guidelines for Heart Failure outline the use of Natriuretic Peptides (NP) in a diagnostic algorithm along with signs and symptoms⁴.

The upper limits of normal in the non-acute setting are 125pg/mL (ng/L) for NT-proBNP, where <125 pg/mL (ng/L) the probability of having heart failure is extremely low. If the ESC cut-off is applied to the Healthy Heart Bus population, the number of individuals who would warrant further investigation would increase from 6 people (6.2%) to 23 people (23.7%) (Table 2). This demonstrates that use of the ESC cut-off would result in almost 4x the number of people potentially requiring follow up and referral for further investigations.

The Healthy Heart Bus Initiative can enable and potentially drive improvements in understanding of heart conditions, and signpost members of the public for how to access information, provision of point of care testing and importantly reach those people who may not be able to easily talk to their Doctor.

NT-proBNP Level for decision making	Number of people	% total people tested
Westcliffe Cardiology Services ≥ 400 pg/mL (ng/L)	6 people	6/97 = 6.2%
European Society of Cardiology cut-off ≥ 125 pg/mL (ng/L)	23 people	23/97 = 23.7%

Table 2: Summary of results when applying ESC NT-proBNP cut-off at ≥ 125 pg/mL (ng/L)

*Unit of measurement - The LumiraDx NT-proBNP test is able to display results in both pg/mL and ng/L

References:

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2. Atrial Fibrillation – Find the missing 300,000" https://www.bhf.org.uk/for-professionals/healthcare-professionals/blog/2019/rushed-to-hospital-when-heart-failure-isnt-diagnosed-early-enough [accessed March 2023]
3. LumiraDx NT-proBNP test www.lumiradx.com/uk-en
4. ESC Guidelines Aug 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure (escardio.org)

Contact Us. We are looking forward to your call!

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