Technoleg Iechyd Cymru
Health Technology Wales

# Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

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| **Topic exploration report number:** | TER441 |
| **Topic:** | AI-assisted ultrasounds for the detection of deep vein thrombosis (DVT) |
| **Summary of findings:** | Deep vein thrombosis (DVT) is a common disease that places patients at significant risk of fatal pulmonary embolism. Currently, detection and diagnosis takes place in specialist settings leading to increased wait times. Technologies that use artificial intelligence may allow for earlier detection and diagnosis of the disease, reducing overall demand on the healthcare system.<br><br>Overall, published evidence evaluating AI-assisted ultrasounds was limited. One primary study externally validated an AI-assisted ultrasound technology (AutoDVT) on two patient groups, one in the UK and one in Germany. The overall 95% CI ranges were 0.82 to 0.94 for sensitivity, and 0.70 to 0.82 for specificity. The authors also undertook cost analysis and reported positive net monetary benefit of £72 to £175 per AI-assisted examination.<br><br>We also identified one ongoing multicentre, prospective pilot study in the UK evaluating AutoDVT. Expected completion date is June 2024. |

## Introduction and aims

Deep vein thrombosis (DVT) refers to a blood clot that has formed within deep veins, usually within the leg. DVT is a common disease that accounts for two-thirds of all venous thromboembolism cases in the UK. In many cases, DVT can lead to a fatal pulmonary embolism, meaning that early detection and diagnosis is key for preventing adverse outcomes. Under best practice guidelines, it is recommended that diagnosis of DVT is achieved within 24 hours.

Currently, DVT is diagnosed in a specialist setting following a positive D-dimer test, and an ultrasound scan or venogram. There is currently no reliable test for DVT that can be used at the point of care in more general healthcare settings such as GPs or nursing homes, resulting in an increased volume of referrals for ultrasound scanning and increased wait times.

Technologies that use artificial intelligence (AI)-assisted ultrasound may enable staff at the point of care to identify and diagnose DVT. AutoDVT was identified by the topic proposer as a specific example of such a technology.

Health Technology Wales researchers searched for evidence on the clinical and cost effectiveness of AI-aided ultrasounds for the detection and diagnosis of DVT.

## Evidence overview

***Guidance***

No guidelines were identified that explicitly mentioned AI-assisted ultrasounds for detection and diagnosis of DVT. However, one NICE guideline that contained potentially relevant recommendations was identified.

NICE Guideline NG158: 'Venous thromboembolic diseases: diagnosis, management and thrombophilia testing' recommends that the result of an ultrasound scan should be provided within 4 hours (1.1.3) or where this cannot be provided, within 24 hours (1.1.4).

***Secondary evidence***

No secondary evidence was identified for this technology.

***Primary Evidence***

One primary study was identified, Kainz et al. (2021), which reported on the training and validation of AutoDVT.

Kainz et al. (2021) used AutoDVT on two external validation groups: patients from an NHS DVT diagnostic clinic (n = 53) and a German DVT clinic (n = 30). The study found that the diagnosis performance results of the technology resulted in a sensitivity that was within a 95% CI range of 0.82 to 0.94, and a specificity of (0.70 to 0.82).

***Economic evidence***

Kainz et al. (2021) also undertook early cost analysis of AutoDVT using a decision tree to estimate the lifetime cost/benefit in terms of quality adjusted life years (QALYs). Sensitivity and specificity from the study was used. Assuming a £20,000 per QALY willingness-to-pay threshold, they reported positive net monetary benefit of £72 to £175 per examination with AutoDVT.

***Ongoing studies***

We identified one ongoing study: ADVENT, a multi-centre, prospective double-blinded pilot study evaluating the automatic detection of DVT through the use of AutoDVT AI. Study completion is expected in June 2024. *Digital Technology*

AI-aided ultrasounds for DVT is a digital health technology and was determined to be a Tier C technology according to the Evidence Standards Framework for Digital Health Technologies**.** Technologies within this classification will provide information that will be used to aid treatment or diagnosis, to triage or identify early signs of a disease or condition, or will be used to guide next diagnostics or next treatment interventions. For technologies of this classification, it is recommended that satisfactory evidence for effectiveness is produced to demonstrate effectiveness of the technology. This includes studies conducted in a setting similar to the UK health and care system, peer-reviewed studies and prospective studies. Evidence to support the claimed benefits of the DHT should include real-world evaluations of its clinical utility, and include 1 or more high-quality studies that support the claimed benefits of the DHT in a relevant setting, showing improvements in relevant outcomes. Similarly, appropriate assessment of the economics of the DHT should be undertaken.

## Areas of uncertainty

- There appears to be limited evidence evaluating the clinical effectiveness of AI-assisted ultrasounds in practice.
- There appears to be limited economic evidence, although the study identified in this report included a net monetary benefit analysis.
  Diagnosis of DVT currently takes place in secondary care. As the technology is intended to be used in primary care, it is unclear how this intervention would embed in or change the current NHS pathway.

## Literature search results

| Health technology assessments and guidance |
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| NICE. (2020). NICE Guideline [NG158]: Venous thromboembolic diseases: diagnosis, management and thrombophilia testing. |
| **Individual studies** |
| Kainz B, Heinrich MP, Makropoulos A, et al. (2021). Non-invasive diagnosis of deep vein thrombosis from ultrasound imaging with machine learning. NPJ Digit Med. 4(1): 137. doi: 10.1038/s41746-021-00503-7 |
| **Ongoing research** |
| ADVENT, A pilot study to evaluate Automatic-DVT diagnostic software v1. (Available at: https://www.isrctn.com/ISRCTN11069056) |

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| **Date of search:** | January 2023 |
| **Concepts used:** | Machine learning, ML, artificial intelligence, AI, deep vein thrombosis, DVT, venous thromboembolism, VTE |