



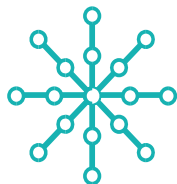
Hand-held ultrasound devices (HUDs) for cardiac assessment and diagnosis of systolic heart failure in the community or primary care setting

Guidance Number:

009 (May 2019)

FIELD: Cardiology

TYPE: Medical device



HEALTH TECHNOLOGY WALES (HTW) GUIDANCE 009 (May 2019)

Hand-held ultrasound devices (HUDs) for cardiac assessment and diagnosis of systolic heart failure in the community or primary care setting

HTW guidance: Hand-held ultrasound devices (HUDs) show promise in the diagnosis of heart failure in a primary care or community setting, but the current evidence is insufficient to support routine adoption. HUDs have the potential to reduce secondary care referrals if heart failure is excluded and to facilitate earlier treatment if confirmed, but convincing evidence is needed to substantiate any clinical and system benefits.

HTW recommends further research to investigate the benefits of implementing HUDs in a primary care or community setting in Wales; see [Further Research](#) for more information.

Why did Health Technology Wales (HTW) appraise this topic?

Heart failure is a common and serious condition that is exerting an increasing burden on cardiology and heart imaging services in Wales. The diagnosis of heart failure can be suspected from clinical assessment and biochemical testing but the use of cardiac ultrasound (echocardiography) is pivotal to either confirming or excluding the diagnosis. Echocardiography is usually done in a hospital setting, but the use of hand-held ultrasound devices means that it can be offered as a quick and portable test to people in a primary care or community setting. This might enable earlier and improved patient management and avoid the need for hospital referral in some cases.

The status of HTW guidance is that NHS Wales should adopt this guidance or justify why it has not been followed. HTW will evaluate the impact of its guidance.

Appraisal Panel considerations

- Heart failure is a major and growing cause of morbidity and mortality in Wales and the Appraisal Panel were convinced of the clinical priority that is being placed on the earlier diagnosis and treatment. The Panel heard that the use of echocardiography (after clinical and biochemical testing) is pivotal to the diagnosis of heart failure and that the use of HUDs has the potential to offer diagnostic cardiac imaging in a primary care or community setting. The Panel agreed on the potential clinical and system value that may be offered by the use of HUDs if systolic heart failure could be accurately diagnosed or excluded. An earlier diagnosis might allow appropriate drug treatment to be started sooner, while an exclusion of systolic heart failure as a cause of symptoms might avoid the need for secondary care hospital referral.
- While the Appraisal Panel acknowledged the promise that the use of HUDs might offer, it considered that the current evidence to support the claimed clinical and system benefits is limited both in quality and quantity. It concluded, therefore, that the routine adoption of HUDs in primary care or community settings in Wales could not be supported.
- The Panel noted that there is some evidence to suggest that training in the use of HUDs can be effectively offered to non-medical as well as medical health professionals. The Panel learnt from the published evidence and expert comments that there are objective parameters that can be measured by HUDs that may help confirm or exclude a diagnosis of heart failure. The Panel were advised in expert comments that heart failure clinics are often led by specialist nurses and supported by cardiac sonographers.
- The Appraisal Panel noted that small studies have identified a relatively high negative predictive value for the use of HUDs in excluding left ventricular systolic function as a cause for heart failure but also noted that no clinical outcome studies are currently available to determine whether clinical decision-making on the basis of a HUD examination is safe and effective. The Panel considered that the use of HUDs in a primary care or community setting has the potential to 'rule out' systolic heart failure as a cause for symptoms and thereby avoid the need for secondary care referral but further evidence is needed to confirm this.
- The Appraisal Panel concluded that drawing conclusions from the economic analysis is likely to be unreliable, given the uncertainties that exist in regard to the clinical evidence.
- The Appraisal Panel concluded that further evidence should be generated to explore the potential value of the use of HUDs in the setting of community based heart failure services in Wales. The Panel recommend that Pilot studies be undertaken to establish the diagnostic accuracy of HUDs for left ventricular systolic dysfunction and to determine clinical outcomes following clinical decisions made on the basis of HUD examinations. The pilot studies should include an assessment of secondary care referrals and costs and provide the option for training in the use of HUDs by non-medical as well as medical health professionals.
- The Panel discussed the potential role of the Wales Cardiac Network and academic institutions in Wales to plan and evaluate the results of the pilot studies. The HTW Appraisal Panel would be eager to re-evaluate HUDs when the results of the pilot studies are available.

EVIDENCE SUMMARY

For a full report of the evidence supporting this Guidance, refer to Evidence Appraisal Report 009.

Context

Over 33,000 people in Wales have been diagnosed with heart failure by their GP. Unlike some cardiovascular conditions, incidence has continued to rise due to the aging population and improved survival after heart attacks. Being able to rule out heart failure when people go to their GP with symptoms, such as breathlessness, would improve patient management and avoid the need for hospital attendance.

Hand-held ultrasound devices (HUDs) are small ultrasound machines ('pocket' sized, approximately the size of a mobile phone) that can be used to assess cardiac structure and function. The portability and 'quick' use of HUDs gives the potential for their use outside of the hospital setting, such as in primary or community care.

Evidence on clinical effectiveness, safety, economic analysis and patient issues

The evidence on the use of HUDs for heart failure assessment or diagnosis in primary or community care is limited. One systematic review was identified, but the scope of the systematic review was broader than the criteria of this evidence review, although it did include two relevant primary studies. An additional two primary studies were identified.

One study was set in the primary care setting, and involved GPs using HUDs to assess people with established heart failure or suspected heart failure. The results were compared with conventional cardiologist-performed echocardiography. The diagnostic sensitivity was 83% and specificity was 78%.

Another study compared GP-performed HUDs with specialist-performed conventional echocardiography; however, this study was undertaken in secondary care and may not accurately reflect the use of HUDs in a primary care or community setting. The sensitivity was 73% and specificity was 75%.

A third study only reported the frequency of cardiovascular abnormalities detected by HUDs and did not include a reference standard (i.e. conventional echocardiography) by which to assess diagnostic accuracy.

The final study assessed the use of GP-performed HUDs in primary care with the results remotely analysed by specialists, compared to conventional echocardiography. There was high specificity for HUDs-based diagnosis across a number of different parameters (93.9% to 99.5%); however, sensitivity was more variable (62.5% to 96.8%). The study showed good agreement between GP and specialist HUD interpretation. Finally, this study also assessed the change in GP clinical management of patients before and after HUDs assessment; the number of patients GPs would have referred for conventional echocardiography reduced from 65.5% to 21.0% following HUDs. Overall, this study showed the potential for HUDs in primary care to optimise patient management and reduce the number of unnecessary referrals for conventional echocardiography.

The studies identified varied greatly in design and in the implementation of the HUD, i.e. whether a specialist or non-specialist used the HUD, and whether a specialist or non-specialist made the diagnosis. There was also variability in the level of training and number of assessments performed by each operator. These factors are likely to have influenced the diagnostic accuracy of HUD implementation. Furthermore, careful consideration is needed in regard to the applicability of these scenarios to the context of NHS Wales.

No evidence on the cost effectiveness of HUDs in primary or community care was identified. HTW developed a cost consequence analysis based on the reported change in clinical management pathway from the Evangelista (2016) study. GPs performing HUDs as part of their assessment with remote evaluation by cardiologists was compared to normal GP assessment (without HUDs). In the base case, there was a £42 increase in cost per consultation with the HUDs approach compared to standard GP assessment, and a per patient increase of £30 with HUDs. However, it should be noted that this economic evaluation is highly sensitive to a range of assumptions that were included in the modelling.

Organisational issues

In 2006, the Wales Cardiac Network Co-ordinating Group published recommendations on the delivery of community echocardiography in Wales. It recommended, as a quality standard, that a “standard echocardiogram” should be done by an accredited operator in anyone with suspected heart failure. Implementation of HUDs in primary or community care may impact initiatives that are already in place using conventional echocardiographic machines.

Other organisational issues would depend on how the HUDs were implemented into primary or community care. If non-specialists, such as nurses or GPs, were to perform the assessment there would need to be adequate training on the use of HUDs. If the HUD were used by a specialist, the extra resource of deploying specialists into primary/community care would need to be considered.

Implementation of HUDs in primary or community care may be of particular benefit to underserved or rural areas, where provision of conventional echocardiography is limited.

Further research

HTW recommends further research to investigate the implementation of hand-held ultrasound devices in the primary or community setting. The undertaking of a pilot studies in NHS Wales (for example via a community-based heart failure service) would be a suitable method of generating further evidence. This could be undertaken by community nurses, GPs, and/or other appropriate healthcare professionals with a specialist interest in cardiology. Clinical and system outcomes should appropriately reflect the impact of HUD assessment, such as the avoidance of hospital referral, the impact of earlier diagnosis and earlier commencement of heart failure treatment.

HTW recommends the involvement of the Wales Cardiac Network as well as local clinical teams and academic bodies in exploring the clinical impact, financial consequences and logistics of introducing hand-held ultrasound devices into a primary care or community setting.

Responsibilities for consideration of this Guidance

Health Technology Wales (HTW) was established by Ministerial recommendation^{1,2} to support a strategic, national approach to the identification, appraisal and adoption of non-medicine health technologies into health and care settings. The HTW Appraisal Panel comprises senior representation from all Welsh boards with delegated authority to produce guidance 'from NHS Wales, for NHS Wales'. The status of HTW guidance is 'adopt or justify'. There is an expectation from Welsh Government that HTW guidance is implemented with adoption regularly audited by HTW.³

The guidance in this document is intended to assist Welsh care system decision makers to make evidence-informed decisions when determining the place of health technologies and thereby improve the quality of care services.

The content of this HTW guidance was based upon the evidence and factors available at the time of publication. An international evidence base was reviewed and external topic experts and HTW committee members consulted to contextualise available evidence to Wales. Readers are asked to consider the generalisability of the evidence reviewed to NHS Wales and that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. It is acknowledged that evidence constitutes only one of the sources needed for decision making and planning.

This guidance does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

No part of this guidance may be used without the whole of the guidance being quoted in full. This guidance represents the view of HTW at the date noted. HTW guidance is not routinely updated. It may, however, be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the guidance given.

Standard operating procedures outlining HTWs evidence review methods and framework for producing its guidance are available from the HTW website.

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Declarations of interest were sought from all reviewers. All contributions from reviewers were considered by HTWs Assessment Group. However, reviewers had no role in authorship or editorial control and the views expressed are those of Health Technology Wales.

Chair, Health Technology Wales Appraisal Panel

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2. Response to Recommendations from the Health & Social Care Committee: Inquiry into Access to Medical Technologies in Wales. February 2015.
3. Gething, V. Letter to all Health Board Chairs re Funding for Sacral Nerve Stimulation in Wales. VG_01655_17. September 2017.



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