What is the clinical and cost effectiveness of hand-held ultrasound devices (HUDs) for cardiac assessment and diagnosis of systolic heart failure, in the community or primary care setting?

**EAR Number:** 009 (May 2019)  
**FIELD:** Cardiology  
**TYPE:** Medical device
Evidence Appraisal Report

What is the clinical and cost effectiveness of hand-held ultrasound devices (HUDs) for cardiac assessment and diagnosis of systolic heart failure, in the community or primary care setting?

1. Purpose of the evidence appraisal report

The Evidence Appraisal Report is a rapid systematic literature search of published evidence and websites to identify the best clinical and economic evidence on health technologies. Researchers critically evaluate this evidence. The draft Evidence Appraisal Report is reviewed by experts and by Health Technology Wales multidisciplinary advisory groups before publication.

2. Health problem

Heart failure is a progressive, complex syndrome when the heart is not efficiently pumping blood around the body, usually following damage to the heart muscle (Senior & Galasko 2005, British Heart Foundation Cymru 2018). Unlike other cardiovascular conditions, heart failure incidence has continued to increase, mainly due to increased survival after heart attacks and increasing number of elderly people. Heart failure is commonly misdiagnosed, particularly in primary care, because signs and symptoms relating to heart failure can also be present in multiple other conditions (Senior & Galasko 2005).

Over 33,000 people in Wales have been diagnosed with heart failure by their GP (British Heart Foundation Cymru 2018). The Welsh Government Heart Conditions Delivery Plan outlines the need for quick and effective diagnosis and treatment of heart conditions, as close to home as possible (Welsh Government 2017). Early diagnosis, monitoring or rule-out of people with heart failure or symptoms indicative of heart failure in the primary or community-based setting can improve patient management and reduce costs.

3. Health technology

Hand-held ultrasound devices (HUDs) are small ultrasound machines (‘pocket’ sized, approximately the size of a mobile phone) that can be used to perform partial or focussed echocardiograms to assess cardiac structure and function (Cardim et al. 2018). They consist of a display unit with a probe that usually provides two-dimensional grey-scale images, which are lower resolution than more high-end systems used for conventional echocardiography. Beyond this, the appearance and capability of the devices can vary (Cardim et al. 2018).

The portability and ‘quick’ use of HUDs gives potential for use outside of the hospital setting, such as in primary or community care. This would enable better diagnosis and management of people with systolic heart failure through improved triage of patients (expert comment, Dr Emma Rees).

Nomenclature associated with HUDs is inconsistent; terms used include hand-held ultrasound device, pocket ultrasound device, pocket echocardiography device, limited ultrasound and
portable ultrasound and hand-held echocardiography (Via et al. 2014, Cardim et al. 2018). Some of these terms can also refer to portable devices that are larger in size than those used for HUDs. In 2018, the European Association of Cardiovascular Imaging published a position statement on the use of HUDs, and recommended HUD as the most appropriate term (Cardim et al. 2018). This appraisal focuses on true hand-held devices; larger portable devices are excluded.

The European Association of Cardiovascular Imaging position statement recommends:

- Appropriate use of HUDs, since they may have a significant positive impact on patient management (Recommendation 1).
- HUDs can be used in the out-of-hospital setting to screen for cardiac pathology or to extend physical examination in order to obtain a tentative diagnosis and support patient management (Recommendation 4).
- Further studies with HUDs to evaluate outcomes and cost-benefit in different clinical settings (Recommendation 10) (Cardim et al. 2018).

4. Evidence search methods

The Population-Intervention-Comparator-Outcomes framework for the evidence appraisal (Appendix 1) was developed following comments from the Health Technology Wales (HTW) Assessment Group and UK experts.

A systematic literature search to study clinical effectiveness was completed on 30 January 2019. The search strategy is available on request. This aimed to identify the following types of evidence:

(i) systematic reviews
(ii) primary studies
(iii) cost-effectiveness studies
(iv) ongoing clinical trials.

Background studies and other papers identified at the scoping stage were also assessed for relevance.

Databases searched included Medline, Embase and the Cochrane database of systematic reviews. In addition, guideline and technology appraisal databases and relevant websites were searched.

The searches returned 3,468 unique articles. Appendix 2 summarises the selection of articles for inclusion in the review.

Patient safety and organisational issues were identified from the papers included in the clinical effectiveness section, and expert advice; no specific searches were undertaken.

5. Clinical effectiveness

The searches identified limited evidence on HUDs for heart failure assessment or diagnosis in primary or community care; the evidence identified reported diagnostic accuracy evidence, but did not include clinical outcomes, patient satisfaction or time to assessment/diagnosis. One systematic review was identified (Galusko et al. 2018); however, the systematic review included use of HUDs in any health care setting and was therefore broader than the scope of this appraisal: some studies relevant to this appraisal were included in the review, and these are summarised in this report.

As the secondary evidence was limited, primary evidence for HUDs in primary and community setting was also considered. Two additional studies were included.
5.1. Systematic review

Evidence on the clinical effectiveness of HUDs in the assessment or diagnosis of heart failure was identified in one systematic review (Galusko et al. 2018). The systematic review included studies conducted in any adult population that reported sensitivities and/or specificities of HUDs and used a ‘gold standard’ reference test. The search period was between January 1978 and January 2018; the review identified 25 studies in total, 2 of which were relevant to this appraisal and involved General Practitioners. The two relevant studies are summarised in Table 1 and 2.

The first study included GPs, but was undertaken in a hospital setting with both hospitalised patients and outpatients with hypertension (Bornemann et al. 2015). The study aimed to evaluate whether GPs were able to use HUDs after 4 hours training, to calculate left ventricular mass index and detect left ventricular hypertrophy. Four GPs were included. The reference standard was a full echocardiogram carried out by an echocardiography technician and interpreted by a cardiologist. Sensitivity and specificity was 73% (95% CI 59% to 87%) and 75% (95% CI 64% to 86%), respectively. Negative and positive predictive values were 83% and 63%, respectively.

The second study was conducted in the primary care setting and aimed to evaluate whether GPs, after eight hours of training, were able to assess left ventricular dysfunction by measuring the septal mitral annular excursion, in patients at risk of developing or who had established heart failure (Mjolstad et al. 2012). Seven GPs participated in the study from three different primary care centres in Norway. The reference standard was a full examination performed by a cardiologist certified in echocardiography, using a laptop scanner (Vivid I; GE Healthcare). Sensitivity and specificity was 83% (95% CI 66 to 93) and 78% (95% CI 64 to 87), respectively. The negative and positive predictive values were 88% and 69%, respectively.
Table 1. Bornemann (2015)

<table>
<thead>
<tr>
<th>Descriptive details</th>
<th>PICO</th>
<th>Quality of study</th>
<th>Observations/notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single centre, Hawaii.</td>
<td><strong>Population</strong>: hospitalised patients and outpatients scheduled for standard echocardiography.</td>
<td><strong>Study design</strong>: 4 primary care physicians (3 family medicine residents and 1 family medicine faculty member) received 4 hours training in limited echocardiography.</td>
<td>This study was not undertaken in the primary care setting, but instead assessed the performance of a GP HUDs assessment versus expert HUDs assessment on inpatients and outpatients.</td>
</tr>
<tr>
<td>n = 101</td>
<td><strong>Index test</strong>: HUDs (Vscan) performed by primary care physicians.</td>
<td><strong>Enrolled patients received HUDs within 14 days of the full echocardiogram.</strong> The primary care physicians were blinded to the full echocardiogram results and patient records. A staff cardiologist interpreted the echocardiogram images from both devices and verified measurements obtained by the echocardiography technician, which then were stored in a diagnostic report in the patient’s medical record.</td>
<td></td>
</tr>
<tr>
<td>Mean 60.5 years old (SD 19 years) 37.6% male; 62.4% female</td>
<td><strong>Reference test</strong>: full echocardiogram performed by echocardiography technician.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recruitment period: not specified.</td>
<td><strong>Outcomes</strong>: Mean difference in LVMI between the primary care physicians and the cardiologist; mean difference of other measurements; sensitivity and specificity.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Results

### Diagnostic accuracy of HUDs performed by primary care practitioners

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity % (95% CI)</th>
<th>Specificity % (95% CI)</th>
<th>PPV % (95% CI)</th>
<th>NPV %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left ventricular hypertrophy</td>
<td>73 (59 to 87)</td>
<td>75 (64 to 86)</td>
<td>63 (48 to 77)</td>
<td>83 (0.73 to 0.92)</td>
</tr>
</tbody>
</table>

### Mean difference between primary care physicians and cardiologists

<table>
<thead>
<tr>
<th></th>
<th>Difference (95% CI)*</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SWT (mm)</td>
<td>0.4 (-0.3 to 1.0)</td>
<td>0.232</td>
</tr>
<tr>
<td>PWT (mm)</td>
<td>1.2 (0.3 to 2.1)</td>
<td>0.007</td>
</tr>
<tr>
<td>LVEDD (mm)</td>
<td>-2.1 (-3.8 to -0.5)</td>
<td>0.013</td>
</tr>
<tr>
<td>LVMI (g/m^2)</td>
<td>0.5 (-6.6 to 7.6)</td>
<td>0.885</td>
</tr>
</tbody>
</table>

*Our hypothesis was that there would be no difference in calculations of LVMI between PCP and cardiologist groups, and our results indeed showed no statistically significant difference. The lack of statistical significance could be related to the relatively small sample size. However, our study was powered to detect a difference of LVMI of 10 g/m^2.*

*Although there was no statistically significant difference in mean LVMI, the variability was large... The effect of this variability can be seen when analyzing the sensitivity (73%) and specificity (75%) for detecting LVH. These sensitivity and specificity values would not normally be considered characteristics of a good clinical test, in which these values would normally be above 80%.*
“Confidence intervals are calculated by standard error of the means.”

"After the completion of the study, the [primary care physicians] voiced that they did not initially feel comfortable with their measurements and that it would have been helpful to have further feedback when they first started performing these exams. It is our belief that if the initial amount of training provided to the [primary care physicians] was increased, and a limited number of supervised echocardiograms occurred following the training, there would have been a large improvement in the variability.”

“...we still believe this is a valuable study. It demonstrates that point-of-care ultrasound measurement of left ventricular mass by a PCP is feasible, although further studies that include protocols with more training and greater initial supervision are needed.”

| CI: confidence interval; HUDs: hand-held echocardiography; LV: left ventricular; LVEDD: left ventricular end diastolic diameter; LVMI: left ventricular mass index; NPV: negative predictive value; PPV: positive predictive value; PWT: posterior wall thickness; SD: standard deviation; SWT: septal wall thickness. |
### Table 2. Mjołstad (2012)

<table>
<thead>
<tr>
<th>Descriptive details</th>
<th>PICO</th>
<th>Quality of study</th>
<th>Observations/notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multicentre (n = 3), Norway.</td>
<td><strong>Population</strong>: patients with at least one of the following: systolic heart failure (32%), previous myocardial infarction (63%) or hypertension (40%).</td>
<td><strong>Study design</strong>: 7 GPs received 8 hours training from a cardiologist certified in echocardiography. Patients were examined by GPs in primary care with the HUDs. A full reference standard test was then performed by a cardiologist in an adjacent room. The cardiologist also performed a HUDs analysis 30 minutes after the reference standard. All the recordings acquired by the GPs were also analysed offline by a second cardiologist certified and experienced in echocardiography.</td>
<td>• The study notes that the first and second cardiologist were blinded to the GPs analysis, but the first cardiologist was not blinded to their own analysis with the laptop scanner. Therefore, the subsequent analysis by the first cardiologist using the HUDs could be influenced by this.</td>
</tr>
<tr>
<td>n = 92</td>
<td><strong>Index test</strong>: HUDs (Vscan) performed by GPs.</td>
<td></td>
<td>• Patients were identified through GP archives for patients with a relevant International Classification of Primary Care diagnosis: K75 myocardial infarction, K77 HF and K87 hypertension complicated. However, the recruitment period was not specified.</td>
</tr>
<tr>
<td>Median 72.5 years old (range 38 to 88 years)</td>
<td><strong>Reference test</strong>: complete transthoracic echocardiogram (Vivid-I laptop scanner) performed by cardiologist.</td>
<td></td>
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</tr>
<tr>
<td>61 (66%) males; 31 (33%) females</td>
<td><strong>Outcomes</strong>: Sensitivity and specificity; agreement of HUDs-based diagnosis by GPs and reference standard by experts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recruitment period: not specified.</td>
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<td></td>
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</tr>
</tbody>
</table>

#### Results

**Diagnostic accuracy of HUDs performed by GP**

<table>
<thead>
<tr>
<th>Left ventricular dysfunction</th>
<th>Sensitivity % (95% CI)</th>
<th>Specificity % (95% CI)</th>
<th>PPV %</th>
<th>NPV %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>83 (66 to 93)</td>
<td>78 (64 to 87)</td>
<td>69</td>
<td>89</td>
</tr>
</tbody>
</table>

*Left ventricular dysfunction by measuring the septal mitral annular excursion.

**Agreement of HUDs performed by GP**

<table>
<thead>
<tr>
<th>Total (n = 92)</th>
<th>GP HUDs and laptop scanner*</th>
<th>GP HUDs analysed by second cardiologist and laptop scanner*</th>
<th>Cardiologist HUDs and laptop scanner*</th>
<th>GP HUDs and cardiologist HUDs**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-0.15 mm (-0.60 to 0.30)</td>
<td>0.08 mm (-0.29 to 0.44)</td>
<td>0.11 mm (-0.10 to 0.32)</td>
<td>-0.26 mm (±3.02)</td>
</tr>
</tbody>
</table>

*In this study, we have shown that it is possible for GPs, after a limited period of focussed training, to use a [HUD] to assess a surrogate marker for global LV function in 87% of the patients with or at risk of developing reduced LV function.*

*There was no significant difference between measurements of sMAE obtained by the GPs and a cardiologist, neither with a laptop scanner and the gold standard M-mode nor with [HUD] with its limited frame rate. When operated by the cardiologist, [HUDs] offered the same accuracy as a laptop scanner when evaluating the sMAE.*

*The training of GPs in our study was limited but specifically tailored to the information they should obtain from this new class of devices. This strategy is fully supported by the recent guidelines issued from the European Association of Echocardiography regarding the use of these new machines in that users should focus their examination to answer a specific question and use this as a tool to support their physical
GP HUDs analysed by second cardiologist versus cardiologist HUDs**

-0.05 mm (±2.68)

*mean difference and 95% CI
**mean difference and 95% limits of agreement

examination.... The sensitivity and negative predictive values were high.”

CI: confidence interval; HUDs: hand-held echocardiography; LV: left ventricular; NPV: negative predictive value; PPV: positive predictive value.
5.2. Additional studies

In addition to the primary studies included in the systematic review above, this review identified two studies within the primary care setting. The first study aimed to assess the feasibility and usefulness of HUDs performed by GPs with remote specialist diagnosis, and compare the impact on patient management with HUDs, compared to conventional echocardiography (Evangelista et al. 2016). The second study aimed to evaluate use of HUDs performed by a sonographer, to identify cardiovascular abnormalities in primary care (Fabich et al. 2016). Study details and characteristics are outlined in Table 2 and 3.

5.3. Ongoing trials

One relevant ongoing trial was identified (Levanger et al. 2019). The study aims to investigate the feasibility, reliability and clinical influence of GP and nurse performed HUDs in patients with suspected heart failure, with subsequent reference imaging and diagnostic by specialists (cardiologists). The study is currently recruiting, with an estimated study completion date of December 2019.
## Table 2. Prospective observational study, Evangelista (2016)

<table>
<thead>
<tr>
<th>Descriptive details</th>
<th>PICO</th>
<th>Quality of study</th>
<th>Observations/notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multicentre (n = 3), Spain. n = 1,312 in the total population, stratified into two groups: Group A (indicated by GPs for conventional echocardiography based on signs/symptoms): Group B (not indicated by GPs for conventional echocardiography, but HUDs performed to complement physical examination):</td>
<td>Population: patients in remote primary care centres. Inclusion criteria were symptoms (eg, shortness of breath, chest pain or palpitations), signs on physical examination (heart murmur, oedema in the feet) or abnormal ECG, suggestive of cardiovascular disease, with no previous diagnosis of heart disease and evaluation by conventional echocardiography.</td>
<td>Study design: Prospective observational study. 14 GPs received 4 days training, consisting of 7 hours per day. The training programme only ended when GPs were able to correctly acquire 4 projections: parasternal long-axis and short-axis views, apical four-chamber view and subcostal view. Prior to HUDs, GPs completed questionnaires for the patients to specify inclusion criteria and what the management of the patient would be: request conventional echocardiography; primary care follow up (3 to 6 months) and discharge; referral to the emergency department. Following HUDs, GPs uploaded data and preliminary diagnosis. 2 experts reviewed the HUDs data and made final diagnosis. Finally, after receiving final diagnosis from experts, GPs reported final management strategy for the patient. Any conventional echocardiography was performed by a blinded independent expert.</td>
<td></td>
</tr>
<tr>
<td>Recruitment period: January 2014 to July 2014</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>The study included people with symptoms suggestive of cardiovascular disease, and may have therefore included patients who do not fit within the scope of this review. A small proportion of patients were indicated to HUDs due to HF: 26 patients (3%) in Group A and 8 patients (1.8%) in Group B. Other reasons for indicated HUDs included dyspnoea, heart murmur, high blood pressure, palpitation and heart pain.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>It is not clear whether the experts making the remote diagnoses were exposed to the preliminary diagnoses provided by GPs - this could lead to bias.</td>
</tr>
<tr>
<td><strong>Group A</strong></td>
<td><strong>Group B</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>859</td>
<td>453</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>43.4%</td>
<td>46.2%</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>67 years (range 15-97)</td>
<td>62 years (range 16-92)</td>
<td></td>
</tr>
</tbody>
</table>

### Results

<table>
<thead>
<tr>
<th>Agreement and accuracy of HUDs findings between family doctors and remote expert diagnosis</th>
<th>Authors’ observations</th>
</tr>
</thead>
</table>
| | “The usefulness of hand-held cardiac ultrasound performed by experts has been confirmed in several studies. The extension of its use to non-
Cardiologists at the point of care has been proposed. However, these non-experts require an appropriate period of training, which is not always feasible, and help with image interpretation.”

“This study showed that family doctors given short adequate training can competently acquire images although their interpretation may be limited and require support from remote experts by telemedicine. Expert diagnosis shows adequate agreement with conventional echocardiography. Indication for conventional echocardiography using this novel strategy was reduced to 30%.”

“This novel strategy may reduce the number of unnecessary conventional echocardiographic studies, shorten waiting list time and prioritise the use of conventional echocardiography depending on the findings of hand-held cardiac ultrasound screenings.”

<table>
<thead>
<tr>
<th>AR</th>
<th>51 (3.9)</th>
<th>0.61 (0.50 to 0.74)</th>
<th>58.3 (43.3 to 73.3)</th>
<th>99.0 (98.3 to 99.6)</th>
<th>68.3 (52.8 to 83.8)</th>
<th>98.4 (97.7 to 99.1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR</td>
<td>79 (5.6)</td>
<td>0.65 (0.56 to 0.74)</td>
<td>72.7 (61.2 to 84.2)</td>
<td>97.7 (96.8 to 98.6)</td>
<td>62.3 (50.9 to 73.8)</td>
<td>98.5 (97.8 to 99.3)</td>
</tr>
<tr>
<td>TR</td>
<td>54 (4.1)</td>
<td>0.42 (0.25 to 0.59)</td>
<td>41.4 (21.7 to 61.0)</td>
<td>98.9 (98.3 to 99.5)</td>
<td>46.2 (25.1 to 67.2)</td>
<td>98.7 (98.0 to 99.3)</td>
</tr>
<tr>
<td>HCM</td>
<td>9 (0.6)</td>
<td>0.53 (0.23 to 0.83)</td>
<td>44.4 (6.4 to 82.5)</td>
<td>99.8 (99.6 to 100)</td>
<td>66.7 (20.6 to 100)</td>
<td>99.6 (99.2 to 99.9)</td>
</tr>
<tr>
<td>LV dysfunction</td>
<td>51 (3.9)</td>
<td>0.51 (0.37 to 0.62)</td>
<td>50.0 (30.4 to 69.6)</td>
<td>92.7 (91.3 to 94.2)</td>
<td>13.9 (6.9 to 20.8)</td>
<td>98.7 (98.1 to 99.4)</td>
</tr>
<tr>
<td>LVH</td>
<td>164 (12.5)</td>
<td>0.70 (0.60 to 0.78)</td>
<td>71.4 (63.1 to 79.7)</td>
<td>97.4 (96.7 to 98.6)</td>
<td>74.4 (66.2 to 82.6)</td>
<td>97.0 (96.0 to 98.0)</td>
</tr>
<tr>
<td>LA dilation</td>
<td>41 (3.1)</td>
<td>0.38 (0.24 to 0.50)</td>
<td>41.5 (25.2 to 57.8)</td>
<td>97.7 (96.8 to 98.6)</td>
<td>37.0 (21.9 to 52.0)</td>
<td>98.1 (97.3 to 98.9)</td>
</tr>
<tr>
<td>AA dilation</td>
<td>122 (9.3)</td>
<td>0.54 (0.43 to 0.71)</td>
<td>54.1 (37.1 to 70.2)</td>
<td>99.1 (98.4 to 99.6)</td>
<td>64.5 (45.4 to 80.2)</td>
<td>98.7 (97.8 to 99.2)</td>
</tr>
</tbody>
</table>

Agreement and accuracy of HUDs findings by remote experts with conventional echocardiography (in group A, n = 774)

<table>
<thead>
<tr>
<th>AR</th>
<th>32 (3.7)</th>
<th>0.84 (0.75 to 0.93)</th>
<th>96.8 (82.0 to 99.8)</th>
<th>98.6 (97.4 to 99.3)</th>
<th>75.6 (53.3 to 87.1)</th>
<th>99.8 (99.1 to 100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR</td>
<td>51 (5.9)</td>
<td>0.88 (0.81 to 0.94)</td>
<td>96.0 (85.4 to 99.3)</td>
<td>98.6 (97.3 to 99.3)</td>
<td>83.5 (70.5 to 91.1)</td>
<td>99.7 (98.8 to 99.9)</td>
</tr>
<tr>
<td>TR</td>
<td>42 (4.9)</td>
<td>0.78 (0.68 to 0.88)</td>
<td>80.9 (66.3 to 90.8)</td>
<td>98.6 (97.4 to 99.3)</td>
<td>77.2 (61.7 to 88.0)</td>
<td>98.9 (97.7 to 99.3)</td>
</tr>
<tr>
<td>HCM</td>
<td>8 (0.9)</td>
<td>0.73 (0.50 to 0.96)</td>
<td>87.5 (44.7 to 99.3)</td>
<td>99.5 (98.6 to 99.8)</td>
<td>63.6 (31.6 to 87.6)</td>
<td>99.9 (99.1 to 100)</td>
</tr>
<tr>
<td>Condition</td>
<td>Frequency</td>
<td>Mean (95% CI)</td>
<td>Range (95% CI)</td>
<td>Median (95% CI)</td>
<td>25th Percentile (95% CI)</td>
<td>75th Percentile (95% CI)</td>
</tr>
<tr>
<td>-----------------</td>
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</tr>
<tr>
<td>LV dysfunction</td>
<td>40 (4.7)</td>
<td>0.72 (0.62 to 0.83)</td>
<td>90.0 (75.4 to 96.7)</td>
<td>97.1 (95.5 to 98.1)</td>
<td>63.1 (49.3 to 75.2)</td>
<td>99.4 (98.4 to 99.8)</td>
</tr>
<tr>
<td>LVH</td>
<td>134 (17.3)</td>
<td>0.77 (0.67 to 0.88)</td>
<td>92.5 (86.3 to 96.1)</td>
<td>96.5 (94.7 to 97.8)</td>
<td>84.9 (77.8 to 90.1)</td>
<td>98.4 (96.9 to 99.1)</td>
</tr>
<tr>
<td>LA dilation</td>
<td>86 (11.1)</td>
<td>0.63 (0.53 to 0.73)</td>
<td>62.5 (50.9 to 72.8)</td>
<td>93.9 (91.8 to 96.5)</td>
<td>54.4 (43.7 to 64.7)</td>
<td>95.6 (93.7 to 96.9)</td>
</tr>
<tr>
<td>AA dilation</td>
<td>50 (6.5)</td>
<td>0.71 (0.61 to 0.82)</td>
<td>76.0 (61.5 to 86.5)</td>
<td>97.9 (96.5 to 98.7)</td>
<td>71.7 (57.4 to 81.8)</td>
<td>98.5 (97.0 to 99.1)</td>
</tr>
</tbody>
</table>

Management of patients by GPs before HUDs and after expert HUDs diagnosis (n = 1,312)
### Management before Hand-held Cardiac Ultrasound

<table>
<thead>
<tr>
<th>Conventional Echo</th>
<th>Referred to Cardiology</th>
<th>Clinical Follow-up</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>859 (65.5%)</td>
<td>41 (3.0%)</td>
<td>247 (18.8%)</td>
<td>165 (12.6%)</td>
</tr>
</tbody>
</table>

### Management after remote expert interpretation of Hand-held Cardiac Ultrasound

<table>
<thead>
<tr>
<th>Conventional Echo</th>
<th>Referred to Cardiology</th>
<th>Clinical-HCU* Follow-up</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>276 (21.0%)</td>
<td>58 (4.4%)</td>
<td>679 (51.8%)</td>
<td>299 (22.8%)</td>
</tr>
</tbody>
</table>

AA: aortic root or proximal ascending aorta; AR: aortic regurgitation; CI: confidence interval; HUDs: hand-held echocardiography; HCM: hypertrophic cardiomyopathy; LVH: left ventricle hypertrophy; MR: mitral regurgitation; NPV, negative predictive value; PPV, positive predictive value; TR, tricuspid regurgitations.
Table 3. Fabich (2016)

<table>
<thead>
<tr>
<th>Descriptive details</th>
<th>PICO</th>
<th>Quality of study</th>
<th>Observations/notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multicentre (n = 1), UK. n = 163</td>
<td><strong>Population</strong>: indications for scans were: ≥75 years, age ≥75 years, cardiac symptoms (chest pain, palpitations, syncope); murmur; chronic obstructive pulmonary disease (COPD) with disproportionate breathlessness; cardiac history in the GP notes (e.g. myocardial infarction); abnormal electrocardiogram (ECG) including atrial fibrillation; high risk of rheumatic disease.</td>
<td><strong>Study design</strong>: The service was offered by newsletter and direct email to all GP practices in Lambeth and Southwark. Two GPs expressed interest but only one practice referred suitable numbers for analysis.</td>
<td>- This study did not include a reference test (i.e. conventional echocardiography as 'gold standard'); therefore diagnostic accuracy of HUDs in primary care was not reported. - The study population included participant that are not within the scope of this review (e.g. inclusion of patients ≥75 years, regardless of symptoms)</td>
</tr>
<tr>
<td>Aged 72 ± 10 years</td>
<td><strong>Index test</strong>: HUDs (Vscan) performed in general practice by level 7 sonographer</td>
<td><strong>Reference test</strong>: None.</td>
<td></td>
</tr>
<tr>
<td>Male 37%; female 63%</td>
<td><strong>Outcomes</strong>: Frequency of cardiovascular abnormalities.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recruitment period not specified</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Results

<table>
<thead>
<tr>
<th>Frequency of abnormalities at the GP practice (n = 163)</th>
<th>Authors’ observations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>This study showed that ‘quick-scans’ detected significant structural disease in 10% of patients with focused indications at a general practice and in 12% of those aged ≥75 years.</td>
</tr>
<tr>
<td></td>
<td>The most common reasons for requesting echocardiography are suspected heart failure or valve disease.3 However, patients with heart failure may be misdiagnosed as having COPD,7 or may have both conditions,8 and may not be screened either with B-type natriuretic peptide levels or echocardiography. We, therefore, included patients with COPD but inappropriate breathlessness as an indication for a ‘quick-scan’.</td>
</tr>
<tr>
<td></td>
<td>‘Quick-scans’ effectively extend the clinical examination and triage the need for standard transthoracic echocardiography.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mild (n = 67)</th>
<th>Significant (n = 16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR</td>
<td>6 (4%)</td>
</tr>
<tr>
<td>MR</td>
<td>15 (9%)</td>
</tr>
<tr>
<td>TR</td>
<td>9 (6%)</td>
</tr>
<tr>
<td>LV dysfunction</td>
<td>10 (6%)</td>
</tr>
<tr>
<td>Dilated aorta</td>
<td>0</td>
</tr>
</tbody>
</table>

AR: aortic regurgitation; HUDs: hand-held echocardiography; LV: left ventricle; MR: mitral regurgitation; TR: tricuspid regurgitations.
6. Safety

None of the evidence identified by this appraisal reported on the safety of HUDs in primary or community care for cardiac assessment.

7. Cost effectiveness

None of the evidence identified by this appraisal reported on cost effectiveness of HUDs in primary or community care for cardiac assessment. HTW developed a health economic evaluation using the pathway illustrated by Evangelista (2016). The structure uses the comparable impact of HUDs on clinical pathway changes to determine the economic impact. The HUDs assessment approach is compared to traditional GP triage. The analysis takes the scope of Wales NHS costs in a 2018 GBP base year.

The health economic evaluation takes the form of a cost consequence analysis. The outcomes are limited to the four triage destinations offered by the Evangelista (2016) analysis: conventional echocardiogram, referral to cardiology, clinical HUDs follow-up, and discharge. The data doesn’t support clinical outcomes further than the initial clinical management pathway.

The health economic model attempts to cost the components described in the literature as closely as possible. Evangelista (2016) evaluates HUDs with the support of two expert cardiologists. The expert evaluation includes a secure electronic file transfer of the data collected within the primary care consultation to be reviewed by two experts. The economic approach assumes that there is a fixed unit cost for the transfer software. The two expert specialist cardiac physiologist (band 6) were assumed to take 5 minutes each to evaluate the HUDs diagnostic. The HUDs evaluation time is incorporated into the GP consultation, with no costs added for informing the patient of the triage result.

GPs were trained for 4 days (7 hour per day) to be able to undertake an evaluation with the HUDs and support of remote interpretation. The fixed-cost portion applied to each consultation requires an accurate estimate of prevalence of use. The number of individuals who would receive a HUDs in the primary care setting is unknown, a range of plausible estimates are used to reflect this uncertainty, the base case uses a figure of 30,000 per annum. Scenario analysis includes estimates ranging from 5,000 to 50,000. Working with the assumption that training would offer an effective coverage for 10 years, the contribution of training costs to each usage is ~£12. This calculation uses a partial coverage approach with the training of the 2,986 registered GPs in Wales. This represents, on average, 2 GPs per practice.

The Vscan (GE healthcare) is reported to cost £5,000 per item, this capital cost is assumed to be spread across a 7-year lifetime of the device, to offer a yearly cost of item. Each GP practice is assumed to have a two units which may be used flexibly. On the assumption that there are 30,000 uses each year within Wales the cost of the item is £21. The digital platform for the secure transfer of data was given a nominal cost of £1 per usage in the absence strong evidence.

Table 5. Unit cost table

<table>
<thead>
<tr>
<th>Conventional Echo</th>
<th>Referred to cardiology</th>
<th>Clinical-HUDs follow-up</th>
<th>Clinical follow-up</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>£108</td>
<td>£128</td>
<td>~£79</td>
<td>£37</td>
<td>£0</td>
</tr>
<tr>
<td>National schedule of reference costs</td>
<td>National schedule of reference costs</td>
<td>combination</td>
<td>PSSRU 201</td>
<td></td>
</tr>
</tbody>
</table>
Table 6. Clinical HUDs cost

<table>
<thead>
<tr>
<th>Health resource</th>
<th>GP consultation</th>
<th>Vscan device</th>
<th>Expert evaluation</th>
<th>Digital platform</th>
<th>GP training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>£37</td>
<td>£21</td>
<td>£8</td>
<td>£1</td>
<td>£12</td>
</tr>
<tr>
<td>Notes</td>
<td>£5000 per device with 7-year life (two devices per practice in 441 practices / 30,000 tests per year).</td>
<td>2* 5 minutes Specialist cardiac physiologist (band 6)</td>
<td>28 hours * 882 GPs (10-year horizon)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference</td>
<td>PSSRU 2018</td>
<td>PSSRU 2018</td>
<td>PSSRU 2018</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

There is an incremental cost per consultation of approximately £42 due to the inclusion of HUDs. The clinical management changes reported by Evangelista (2016) highlights the inclusion of HUDs as an improvement to triage which may reduce the number of conventional echocardiograms undertaken. The 1,312 patients in the clinical management pathway represent a total cost of £155,700 for the conventional treatment arm and £195,200 for the HUD approach. The per patient increase to cost associated with HUDs is £30. An additional 583 patients are referred for standard echocardiogram under the traditional route (GP assessment without HUDs). An additional 432 patients have a follow-up HUDs GP consultation under the HUDs arm; there is also an increase in cardiology referrals and discharged patients in the HUDs arm. Given 30,000 initial consultations per year, there would be an increase in costs by £903,000.

Findings are highly sensitive to a range of assumptions within the modelling. The number of GP consultations within a year impacts the allocation of training and device costs to the extent that the HUDs contact would reduce in cost to ~£66 with an increase of contacts to 50,000. Decreasing the number of HUD contacts to 5,000 increased the per consultation to £246. Contact numbers represented the largest influence on cost effectiveness, the number of contacts required for HUD to be cost neutral was ~74,000. The cost neutral consultation level would result in each clinician seeing approximately 85 patients per year specific to HUD. The direct cost of the HUDs consultation would have to reduce by around £20 to result in a cost neutral position. Fewer trained clinicians, 1 per practise, led to a decrease in HUD consultation costs to £73.

7.1. Scenario analysis

The broad adoption of HUD would appear to be cost prohibitive; consultation with experts has helped develop alternative deployment strategies which will be investigated in the scenario analysis. A prominent feature of the base case analysis is the high number of devices and trained GPs, centralising HUD usage may result in a more cost effective outcome. Expert consultation advised that the yearly number of consultations to be around 1,250. The coverage model looks to have a HUD per 250,000 population, a total of 14 in Wales. This centralisation approach decreases the direct fixed costs applied from training and device costs but incurs primary to primary referral costs in the form of an additional GP consultation for patients not registered at one of the 14 practises. The economic model estimates HUD to be more costly compared to standard care by ~£33 per patient.

Expert consultation recommended a modelling approach built on what may be realistically achieved within the Welsh NHS setting; this approach deviates from the deployment structure of Evangelista (2016). In this scenario, GPs with Specialist interest are trained in 2 days and would see enough patients to develop sufficient expertise to not require remote expert evaluation. Aligning more closely with current practice, the standard care arm is unable to directly refer to conventional echo and therefore incurs an additional cardiology consultation cost. HUD triage
access to conventional echo remains direct. The centralised and optimised approach results in significant cost savings associated with the use of HUD. Standard care incurs increased costs whilst HUD is lower cost than other scenarios, this results in a saving of approximately £68 per patient.

8. Organisational issues

In 2006, the Wales Cardiac Network Co-Ordinating Group published recommendations on the delivery of community echocardiography in Wales (Cardiac Networks Co-Ordinating Group 2006). It recommends a “standard echocardiogram” as the quality standard for community echocardiography, for people with suspected heart failure, and that the assessment should be performed by accredited operators. Health boards are implementing service models to improve diagnosis of heart failure in primary care, which in some cases includes provision of conventional echocardiography (E Rees 2019, expert comment). Therefore, implementation of HUDs in primary or community care may impact these initiatives.

Other organisational issues for the introduction of HUDs in the primary or community care setting depend on: 1) who will perform the HUDs and 2) who will evaluate the imaging and provide diagnosis. If the HUDs is performed by non-specialists, such as GPs or primary care nurses, they will need to undergo training on the use of HUDs. Additional training will also be necessary if they are required to make the initial diagnosis or rule out of heart failure; the amount of training required will depend on the type of assessment that will be required. In the three studies identified by this evidence review where HUDs was undertaken by GPs, the training varied from 4 hours of training (with no formal assessment of competency on completion) to 4 days of training with an assessment of competency before completion of the training. In the study that implemented 4 hours training, the GPs gave feedback that they did not initially feel comfortable without further assessment of their HUDs measurements; the authors noted that additional support/training may have reduced variability and increased diagnostic accuracy. The systematic review also noted that the more time performing HUDs, the better the accuracy, and that further studies are needed to determine the training threshold, allowing users to practice both under supervision and independently.

If the HUDs needs to be performed by a specialist, the extra resource of deploying an appropriate number of specialists into the primary/community care setting is required.

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

9. Patient issues

None of the evidence identified for this appraisal did not report on patient experience or issues relating to HUDs in primary or community care setting for cardiac assessment.

10. Conclusions

The aim of this review is to identify and assess evidence on the effectiveness of HUDs for the assessment and diagnosis of heart failure, when used specifically in primary or community care.

One relevant systematic review was identified; this had broader inclusion criteria than the scope of this review, but included two studies relevant to the use of HUDs in the primary or community setting. We also identified two additional primary studies.
The evidence identified for this appraisal varied in study design; whether a specialist or non-specialist performed the HUDs, and whether a specialist or non-specialist made the diagnosis. The type and amount of training received by non-specialist HUDs operators in each study also varied considerably, as did the number of HUDs each operator performed. All these factors are likely to affect the diagnostic accuracy reported by each study when HUDs are used to detect heart failure. The differences between the studies means that pooled analysis of diagnostic accuracy would not be appropriate. Furthermore, careful consideration is needed about the applicability of these results to NHS Wales.

One study was set in the primary care setting, with GPs assessing people with developed or suspected heart failure versus cardiologist-performed echocardiography; sensitivity was 83% and specificity was 78%.

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

The third study only reported 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 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 types of findings (93.9% to 99.5%); sensitivity was more variable (62.5% to 96.8%). The study showed good agreement between GP and specialist HUDs 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 indicate for conventional echocardiography greatly reduced from 65.5% to 21.0% following HUDs. Overall, this study showed potential for HUDs in primary care to optimise patient management and reduce the number of unnecessary referrals to conventional echocardiography.

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 (2019) 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, with 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.

11. 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.
12. Contributors

This topic was proposed by Dr Abbas Zaidi, Consultant Cardiologist (Cardiff & Vale UHB).

The HTW staff and contract researchers involved in writing this report were:

- L Elston - main author and systematic literature reviewer
- J Washington - literature search
- T Winfield - economic appraisal
- D Jarrom - quality assurance

The HTW Assessment Group advised on methodology throughout the scoping and development of the report.

A range of clinical experts from the UK provided material and commented on a draft of this report. Their views were documented and have been actioned accordingly. All contributions from reviewers were considered by HTW’s Assessment Group. However, reviewers had no role in authorship or editorial control, and the views expressed are those of Health Technology Wales.

Experts who contributed to this appraisal:

Dr Abbas Zaidi, Consultant Cardiologist
Dr Adrian Ionescu, Consultant Cardiologist
Dr Damian Pathy, GP with Special Interest in Cardiology
Dr Emma Rees, Senior Lecturer/Clinical Scientist
Prof Alan Fraser, Consultant Cardiologist
Dr Sally Lewis, GP
13. References


# Appendix 1. PICO framework

<table>
<thead>
<tr>
<th>Included</th>
<th>Excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population</strong></td>
<td><strong>Excluded</strong></td>
</tr>
<tr>
<td>People with known or suspected heart failure who are being assessed in a community/primary care setting</td>
<td>People presenting with murmur and suspected stenosis</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td></td>
</tr>
<tr>
<td>HUDs (any device)</td>
<td></td>
</tr>
<tr>
<td><strong>Comparison/comparators</strong></td>
<td></td>
</tr>
<tr>
<td>Medium-sized “portable” echocardiography machines used in community heart failure clinics</td>
<td></td>
</tr>
<tr>
<td>Large echocardiography machines used in hospital following GP referral.</td>
<td></td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>Device diagnostic accuracy</td>
<td></td>
</tr>
<tr>
<td>Clinical outcomes</td>
<td></td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td></td>
</tr>
<tr>
<td>Time to assessment/diagnosis</td>
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</tr>
<tr>
<td><strong>Study design</strong></td>
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</tr>
<tr>
<td>No restriction</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 2 - PRISMA flow diagram outlining selection of papers for clinical and cost effectiveness

Records identified through database searching (n = 4,720)

Additional records identified through other sources (n = 18)

Records after duplicates removed (n = 3,468)

Records screened (n = 3,468)

Records excluded (n = 3,370)

Full-text articles assessed for eligibility (n = 99)

Full-text articles excluded (n = 93)

Papers included in Evidence Appraisal Report (n = 6)

- Systematic reviews (n = 1)
- Primary studies (n = 4)
- Ongoing studies (n = 1)