



HEALTH TECHNOLOGY WALES (HTW) GUIDANCE 029 (March 2021)

Point-of-care ultrasound to diagnose gallstone disease

HTW Guidance:

The use of portable point-of-care ultrasound (POCUS) to diagnose gallstone disease shows promise, but the current evidence is insufficient to support routine adoption.

Studies to date have primarily considered the diagnostic accuracy of POCUS but uncertainties remain about the effectiveness of POCUS when used alongside other investigations as part of clinical decision-making.

Due to uncertainties around clinical effectiveness, in particular the waiting time before receiving a scan, reliable conclusions about the potential economic consequences of using POCUS cannot be drawn.

Further research is recommended to demonstrate the clinical and cost effectiveness of portable POCUS in emergency and acute care settings.

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

Gallstones are usually asymptomatic, but in a small number of cases (2 to 4%) gallstones can become trapped within the biliary system and can cause abdominal pain, inflammation and infection. This can further lead to more serious conditions that involve inflammation of the gallbladder, biliary tree and pancreas, such as cholecystitis, cholangitis and pancreatitis.

Diagnosing gallstones as a possible cause for abdominal pain in an acute or emergency care setting usually requires referral to a radiology department for an ultrasound, performed by an accredited technician. Effective point-of-care ultrasound could reduce the need for a radiology referral and therefore shorten time to diagnosis and treatment of gallstone disease and associated conditions.

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.

Evidence Summary

Refer to Evidence Appraisal Report 029 (EAR029) for a full report of the evidence supporting this Guidance.

HTW researchers searched for and appraised evidence on the effectiveness and cost effectiveness of using hand-held or portable ultrasound to aid diagnosis in people with suspected gallstones.

Six studies were identified that evaluated the diagnostic accuracy of portable point-of-care ultrasound (POCUS). These studies varied in design including the use of different portable POCUS devices, different POCUS operators as well as the training given, and different reference standards (e.g. radiology ultrasound, final diagnosis at discharge). Across these six studies, diagnostic sensitivity ranged from 75% to 100% and specificity ranged from 84.4% to 100% for portable POCUS.

Two of the six studies included a comparator. The first compared portable 'laptop-sized' POCUS against formal ultrasound, with final diagnosis as the reference standard; specificity was similar for both ultrasound methods, but sensitivity was higher with formal ultrasound. The second study compared handheld POCUS carried out by non-expert operators with handheld POCUS carried out by expert operators, with formal ultrasound as the reference standard. Sensitivity and specificity were both higher when handheld POCUS was performed by expert operators.

An economic analysis developed by HTW showed hand-held/portable POCUS to be cheaper but less effective than radiologist-performed ultrasound. The resulting ICER of £58,631 per QALY indicated that POCUS was cost effective at the £20,000 per QALY threshold (note that, in this scenario, an ICER above £20,000 per QALY is cost effective because it indicates that the money saved per QALY lost could be better spent elsewhere). However, the result was not robust across all scenario analyses. In particular, when no difference was assumed between POCUS and radiologist-performed ultrasound in waiting time for scanning, POCUS was found to be more costly and less effective than radiologist-performed ultrasound (i.e. dominated). In a threshold analysis, it was found that the difference in waiting time for scanning needs to be 4.2 hours or greater for POCUS to be cost effective. In probabilistic sensitivity analysis, POCUS was found to have a 49% probability of being cost effective at a threshold of £20,000 per QALY.

The appropriate mechanism for patient engagement was determined and the patient perspective was considered where possible. The mechanism determined for this appraisal was a high-level literature search on patient and carer issues; the search did not identify any additional evidence that was not already included in the main evidence review.

Appraisal Panel considerations

- The Appraisal Panel learnt that portable POCUS is not currently used in Wales and that radiology-performed ultrasound represents the current standard of care for people with suspected gallstones in an acute or emergency setting. However, there is growing interest in the use of POCUS for a range of indications, and a clinical expert noted that there is also interest in including portable ultrasound as a complementary clinical skill in medical training.
- The Panel were informed by clinical experts that operator expertise and the nature of the equipment used are critical in influencing diagnostic performance for POCUS and radiology ultrasound. Clinical experts also noted that gastroenterologists in the UK do not routinely carry out ultrasounds and so additional training and clinical governance standard setting would be needed if POCUS was recommended for adoption.
- Clinical experts noted that even with conventional ultrasound, repeat scans are often needed. Stabilising patients who are acutely unwell prior to ultrasound can improve the quality of

imaging obtained. As a result, introducing a delay before obtaining a gold standard test may be of clinical advantage.

- Clinical experts considered that, in practice, gastroenterologists performing POCUS do not make clinical decisions based on POCUS alone, but that the results would form part of their decision-making alongside other assessments including the clinical characteristics of the presentation. The Appraisal Panel agreed that there may be potential benefits in evaluating POCUS as an adjunct to other investigations in the patient care pathway.
- The experts noted that there are a wide range of possible presentations for people with gallstones, such as acute abdominal pain or jaundice. Conversely, abdominal pain can be due to a wide range of causes other than gallstones, and sometimes gallstones are found incidentally when they are not the cause of the abdominal pain. Consequently, when investigating such symptoms, incidental findings such as unexpected malignancy are not uncommon and are of potential clinical importance. The Appraisal Panel considered that, due to these overlapping conditions, there would be potential benefits to broadening the indication of POCUS beyond just the diagnosis of gallstones specifically and that the reporting of other additional intra-abdominal abnormalities when using POCUS for suspected gallstones may be a valuable clinical outcome.
- In considering the appropriate clinical setting for the use of POCUS, the clinical experts explained that its use in an acute or emergency secondary care setting is the most appropriate to consider at the moment. There may be the potential for the use of POCUS in a primary care community setting for the diagnosis of gallstones and other intra-abdominal abnormalities, but this seems to be less relevant to the patient care pathway at present given the limited evidence available.
- In view of these considerations, the Appraisal Panel concluded that it is important to consider not just the diagnostic accuracy of POCUS as compared with conventional radiology ultrasound but also to determine its impact on overall clinical decision-making and management. The Appraisal Panel noted that no such clinical studies are currently available, and uncertainty therefore remains about the possible overall clinical benefits of POCUS in an acute or emergency setting.
- The Panel considered the possible resource implications of implementing POCUS, given that it appears that its diagnostic accuracy is less than that of conventional radiology ultrasound. The experts explained that liberating time spent on radiology imaging could be of potential significance given the current pressures on the service and the waiting times.
- The Appraisal Panel considered the economic analysis developed by HTW and noted that there are multiple sources of clinical and system uncertainty associated with this analysis. They agreed, therefore, that it is difficult to conclude whether POCUS is a cost-effective investigation based on the current evidence.
- The Appraisal Panel concluded that although POCUS shows promise, the current evidence is insufficient to support routine adoption. The panel agreed that the varying levels of training and experience reported across the studies reinforced the need for standardised, accredited operator training and setting of clinical governance standards, and that levels of training should be recorded as part of any future data collection.
- The Appraisal Panel considered that further research is merited on this technology and that this research should focus on:
 - the use of portable POCUS in the investigation of patients with acute abdominal symptoms in an acute and emergency secondary care setting such as Emergency Departments and medical and surgical admissions units
 - the comparative diagnostic accuracy of portable POCUS imaging compared to standard care, as well as its impact on subsequent patient management, including the discovery of incidental diagnoses such as malignancy
 - the complementary use of portable POCUS alongside current management strategies.

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.

Acknowledgements. HTW would like to thank the individuals and organisations who provided comments on the draft Evidence Appraisal Report or HTW guidance.

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

1. National Assembly for Wales, Health and Social Care Committee. Access to medical technologies in Wales. December 2014.
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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