Recommendation from the Danish Health Technology Council concerning

pocket-sized handheld ultrasound devices for point-of-care examination of patients in emergency departments

Recommendation from the Danish Health Technology Council:
Based on the analysis of pocket-sized handheld ultrasound devices for point-of-care examination of patients in emergency departments, the Danish Health Technology Council does not recommend general implementation of handheld ultrasound devices.

About this recommendation:
This recommendation is based on the assessment that, on the current basis, there is no overall added value from using handheld ultrasound devices compared to non-handheld ultrasound devices because the literature review indicates uncertainty about the risk of false negative findings. The Danish Health Technology Council notes that this is of particular importance in an emergency care setting.

The Danish Health Technology Council recognises that the technology is developing rapidly and that some elements relating to the use of handheld ultrasound devices are worth examining in more detail. ultrasound examinations in emergency care settings are none the less part of an overall diagnostic process that includes an objective examination, the patient's medical history and potential paraclinical examinations.

The Danish Health Technology Council acknowledges that local conditions may favour the use of handheld ultrasound devices and acknowledges that, to some extent, the technology has already been implemented for daily use in certain emergency departments. The Danish Health Technology Council recommends that any use of handheld ultrasound devices is considered part of a department’s overall ultrasound-equipment capacity.

The Danish Health Technology Council emphasizes the importance of ensuring that data from handheld ultrasound devices is documented and transferred to patient administration systems for training and patient safety purposes. Furthermore, the Danish Health Technology Council notes that emergency departments should generally be wary of handheld ultrasound devices leading to increased risk of unnecessary diagnostic testing.

Validity period: This recommendation is valid until Q1 2025, as the technology is developing continuously and as it is assumed that more clinical studies and local experience with the technology will influence the evidence base significantly.

About the technology	Handheld ultrasound devices are small, pocket-sized ultrasound devices, often comprising one or more probes and linked to a monitor the size of a mobile phone or tablet.
Patient population	This recommendation concerns adult patients with suspected acute medical conditions indicating the following focused ultrasound protocols as part of the initial diagnosis in the emergency departments: extended focused assessment with sonography for trauma (eFAST), focused cardiac ultrasound (FoCUS/FHUS), focused lung ultrasound (FLUS), focused abdominal ultrasound (FAS/FAUS) and focused two-point limited compression ultrasound (LCUS).
Scope	This recommendation applies to Danish public hospitals.
Implementation	If there are local conditions favouring the use of handheld ultrasound devices, the individual hospital should be aware of measures to ensure the availability of handheld ultrasound devices for clinicians in daily workflows. In particular, the individual emergency department should consider conditions such as where the handheld ultrasound devices are located, whether staff can hold on to the handheld ultrasound device during their entire shift, where the devices are stored when not in use, including whether they are in a locked facility, and how users can access the devices. If handheld ultrasound devices are used, it is important to consider how data from the handheld ultrasound devices is documented and transferred to patient administration systems. Furthermore, legal and security concerns should be considered if the product is used with external monitors, e.g. smartphones or tablets, or if the device uses cloud-based solutions.
Tendering procedure	No proposal for national tendering procedure.

About the analysis	This recommendation from the Danish Health Technology Council is based on the expert committee's analysis report regarding pocket-sized handheld ultrasound devices for point-of-care examination of patients in emergency departments. The purpose of the analysis is to answer the following question: *Should pocket-sized handheld ultrasound devices be used for focused point-of-care ultrasound examinations in emergency departments?*
Clinical effectiveness and safety	The analysis of clinical effectiveness and safety includes 31 studies. A total of 24 studies examine the diagnostic accuracy of pocket-sized handheld ultrasound devices (HHUSD) compared to non-handheld ultrasound devices, while 10 studies examine the image quality of HHUSD compared to non-handheld ultrasound devices. Assessed on sensitivity, the HHUSD used are inferior to the non-handheld ultrasound devices across studies and across the included target conditions. The literature therefore indicates a potential risk of false negative findings when using HHUSD compared to using non-handheld ultrasound devices. The literature shows that if HHUSD is assessed on specificity, it tends to be assessed as being non-inferior or almost non-inferior to non-handheld ultrasound devices. The literature therefore indicates no risk of false positive findings when using HHUSD compared to non-handheld ultrasound devices. Of note, the literature does not provide any information about the consequences of the diagnostic accuracy of HHUSD. The POCUS examination is generally never used as a stand-alone examination and the findings are therefore always interpreted in the context of the patient anamnesis, the objective examination and other paraclinical examinations. With regard to all of the studies, the expert committee's assessment is that the literature is generally outdated, as it pertains to studies of older versions of HHUSD. Furthermore, the expert committee assesses the methodology and execution of the studies to be too heterogeneous for drawing any overall conclusion based on the literature. Therefore, the expert committee concludes that the literature identified should not be used to answer the question of whether HHUSD should be used for focused point-of-care ultrasound examinations in emergency-care settings. The expert committee points out that the image quality of HHUSDs is poorer than that of non-handheld scanners, but also notes that the poorer image quality does not necessarily have a negative influence on diagnostic decision-making.
Patient perspective	The systematic literature search did not identify any relevant literature for answering the review question with regard to the patient perspective. The expert committee states that patient preferences and patient concerns do not affect the use of HHUSD compared to non-handheld ultrasound devices, but ultrasound devices can generally help promote physician-patient dialogue.

	HHUSD have already been partly implemented at Danish emergency departments. While non-handheld ultrasound devices are available at all emergency departments, HHUSD have been procured at 11 out of 21 emergency departments. There is an observed large difference in the *quantitative availability* of ultrasound devices across emergency departments, when comparing total number of ultrasound devices to total number of daily patients. Physicians generally experience and expect that HHUSD can lead to more POCUS examinations in emergency departments; however, this cannot be concluded from the data used in the analysis.
Organisational implications	Based on the analysis, no substantial differences were identified regarding workflow and time consumption in relation to focused POCUS examinations, when comparing HHUSD to non-handheld ultrasound devices. However, availability of devices at emergency departments does have crucial significance in terms of workflow and time consumption. Availability is reported as dependent on local conditions at the emergency department, including conditions pertaining to when the decision to perform POCUS is made, the number of ultrasound devices, where the devices are located, as well as their mobility and size. HHUSD are described as particularly advantageous for patients in isolation, due to hygiene concerns. Furthermore, HHUSD are advantageous in focused POCUS examinations of unstable patients, because, in certain situations, use of an HHUSD enables the physician to perform the ultrasound examination faster than with a non-handheld ultrasound device. Emergency care physicians express different preferences and opinions with regard to HHUSD primarily based on the experienced image quality , the possibility and need for image documentation, as well as use of the technology for training and supervision. The expert committee assesses that the organisational implications examined speak neither against nor in favour of using HHUSD in POCUS examinations at emergency departments. However, the expert committee assesses that local conditions, circumstances and the individual preferences of physicians, are significant for whether HHUSD can be considered a valuable supplement to existing ultrasound devices.

Health economics

The cost analysis estimates that HHUSD is [redacted] less costly per use compared to non-handheld ultrasound devices. The expert committee notes that the expected service life affects the average costs of HHUSD. Furthermore, the expert committee notes that in a scenario where both types of ultrasound devices is used with increased time consumption changes the result of the analysis resulting in HHUSD being more costly compared to non-HHUSD. In another scenario potential time savings from using HHUSD make the incremental cost even lower in favour of HHUSD. The expert committee notes that inputs in the cost analysis are highly operator- and location-dependent, and that there is significant uncertainty about population size. Therefore, the expert committee assesses that the results neither support nor oppose the use of HHUSD.

The analysis estimates that national implementation of HHUSD over a five-year period will result in a budget impact of [redacted]. The choice of HHUSD product and the expected service life of the product has an impact on the size and timing of the budgetary impact.

The expert committee notes that HHUSD is often purchased as operational purchases that can be made by each department, while non-handheld scanners are purchased as larger strategic purchases as part of regions/hospitals technology pools. This means that is currently easier for each department to acquire HHUSD compared to acquiring non-handheld scanners.

The quality of evidence

Only published literature is used for the analysis of clinical effectiveness and safety. The quality of the evidence base for the remaining perspectives is assessed qualitatively.

Clinical effectiveness and safety: Studies of diagnostic accuracy were assessed using the QUADAS-2 tool with regard to risk of bias, as well as generalisability. There is a significant risk of bias and/or concerns regarding generalisability in 20 out 24 randomised studies. The subsequent GRADE assessment shows that there is very low to moderate confidence in the meta-analysis estimates of sensitivity and specificity with regard to HHUSD. The overall assessment of the evidence therefore indicates very low confidence in the results of the literature review, see section 8.5

Patient perspective: There is no evidence base to support this perspective.

Organisational implications: The evidence base consists exclusively of empirical data collected through a questionnaire and interviews, and no formal quality-of-evidence assessment was therefore performed. Regarding the validity of the questionnaire and the interviews, there are concerns about the representativeness of respondents and interviewees. The results concern aspects with high preference-sensitivity and operator-sensitivity, and the results of the studies may therefore be associated with significant uncertainty, see section 10.6.

Health economics: No formal quality-of-evidence assessments were made with regard to the health economics perspective.

About the recommendation from the Danish Health Technology Council

The Danish Health Technology Council's recommendation is intended as an aid for regions when deciding on the use of a given health technology or with regard to organising a treatment area. The analysis report includes a review of the following perspectives: 1) clinical effectiveness and safety, 2) patient perspective, 3) organisational implications and 4) health economics.

This recommendation is based on the Danish Health Technology Council's analysis report regarding pocket-sized handheld ultrasound devices for point-of-care examination of patients in emergency care, which was prepared collaboratively by the expert committee and the secretariat. The analysis report was prepared with outset in the analysis design and the Danish Health Technology Council's process guide and methodological guidelines. These documents as well as the expert committee's terms of reference are available on the Danish Health Technology Council's website.

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