NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of Diagnostics Guidance 5; SonoVue (sulphur hexafluoride microbubbles) - contrast agent for contrast enhanced ultrasound in liver imaging

Final recommendation post consultation
Transfer the guidance to the 'static guidance list' and signpost users from the landing page to the evidence which addresses the research recommendations.

1. Background

This guidance was issued in August 2012

At the GE meeting of 06 October 2015 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted and the responses are presented below.

2. Proposal put to stakeholders

Transfer the guidance to the 'static guidance list' and signpost users from the landing page to the evidence which addresses the research recommendations.

3. Rationale for selecting this proposal

Changes in clinical practice, technology costs or evidence that would lead to a change in the adoption recommendations of the original guidance have not been identified. Evidence directly addressing the research recommendations and supporting the assumptions made in the original guidance was identified (generated by NICE's research facilitation activities). It is therefore proposed that the guidance is placed on the static list.

4. Summary of consultation comments

Comments received during consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments received, and are not endorsed by NICE, its officers or advisory committees.

Respondent: BRACCO **Response to proposal:** <u>Section 6.41</u> A new paper (Wildner at al. Ultraschall in Med 2015; 36:132–139) has been published addressing the potential of discrimination of HCC and CCC in patients with cirrhotic liver, which was questioned by the AASLD guideline leading to the removal of CEUS. The AASLD guideline conclusion was based on an imaging protocol using static images from arterial and portal phase, as it is the standard for CT and MRI imaging. This is however not taking advantage from the potential of CEUS to record dynamic video sequences of up to 6-8 min duration. The paper of Wildner at al has demonstrated, that including the full dynamic information HCC and CCC can be discriminated based on the time kinetics of contrast wash-out (CCC show a fast washout, while HCC usually show a much slower/delayed washout) and the dynamic progression of washout. Using this information HCC can be discriminated from CCC in patients with liver cirrhosis.	**Comments from the Diagnostics Assessment Programme** Thank you for your comments, which have been considered by NICE. This paper is an analysis of a subset of samples from the DGUM study; this study did not meet the inclusion criteria defined in the assessment protocol for the original assessment as it used the incorrect comparator.

Paper signed off by: Carla Deakin, 18 November 2015

Contributors to this paper:

Technical Lead: Brendan Mullaney

Technical Adviser: Sarah Byron

Project Manager: Robert Fernley