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*ICUS is the only international organization
exclusively devoted to
contrast-enhanced ultrasound ("CEUS").*

*Membership in ICUS is free.
Sign up at:*

www.icus-society.org

LETTER FROM THE CO-PRESIDENTS

Dear Colleagues,

As we enter the new year, we are well aware of the increasing complexities of the health care environment worldwide. Yet no matter where we live and no matter what medical subspecialty we represent, we share the same core professional goal -- providing excellence in patient care.

ICUS was formed to further that goal by facilitating the growth of contrast-enhanced ultrasound (CEUS) in order to improve the safety, accuracy and efficiency of diagnosing a variety of clinical abnormalities, ultimately improving patient care and saving lives.

Since ICUS was launched in September 2008, the outpouring of interest in CEUS worldwide has become quite evident. ICUS already has members in 26 countries, representing diverse medical imaging specialties. In addition, we were pleased to welcome representatives of 11 companies to the first ICUS Industry Roundtable held December 1st in Chicago.

Continued on page 2



ICUS sponsors its first Industry Roundtable December 1st in Chicago

Representatives of 11 companies from the U.S., Europe and Japan met with ICUS board members and representatives of the Sonnenschein, Nath & Rosenthal law firm, which assists ICUS at no cost as a public service. The successful Industry Roundtable set the stage for future ICUS leadership on initiatives relating to FDA "black box" warnings, standards of care, communications, education, new applications, public policy, international outreach, and similar matters relating to the CEUS field

Co-Presidents Letter (cont.)

Based on the input we have received from our members and from industry, ICUS has developed an ambitious set of goals, which include the following:

1. Eliminate the "black box" warnings imposed on CEUS agents in the United States, utilizing the latest scientific research data demonstrating the safety of these agents.
2. Establish CEUS as an important component of the standard of care. To that end, ICUS has begun preparing a position paper (accreditation document) establishing a minimum standard of care for ultrasound/echo laboratories world-wide.
3. Expand awareness of the clinical safety, utility, and cost effectiveness of CEUS agents through educational outreach efforts aimed at medical professionals, patients, hospitals, payors and the media.
4. Coordinate strategic communications with regulatory and policy making bodies, expanding the positive grassroots dialogue initially established with the FDA.
5. Help coordinate scientific research initiatives relating to CEUS and its impact on improving outcomes, lowering costs, and prevention.
6. Facilitate the development of new applications for CEUS.
7. Provide members with the latest information on CEUS developments worldwide. This is already being done through the monthly ICUS Newsletter and the ICUS Weekly News Monitor, both of which are emailed to all members at no cost. In addition, the ICUS website is filled with information and links to important CEUS studies and conferences. Your contributions to any of these resources are always welcome.
8. Sponsor an international conference for ICUS members October 21-23, 2009, at the Knickerbocker Hotel in Chicago. For more information please visit www.bubbleconference.com.

We encourage you to keep us informed of your experiences with CEUS and to encourage your colleagues to join the organization by visiting www.ICUS-Society.org. There is no cost for membership.

With best wishes for a happy and HEALTHY 2009,

Steve Feinstein & Barry Goldberg
Co-Presidents

Recent News



Acute Mortality in Hospitalized Patients Undergoing Echocardiography With and Without an Ultrasound Contrast Agent (Multicenter Registry Results in 4,300,966 Consecutive Patients)

A recent study sought to define acute mortality in a large multicenter cohort of hospitalized patients undergoing clinically indicated echocardiography with and without use of an ultrasound contrast agent. Although the United States Food and Drug Administration recently relaxed the issued warnings for perflutren-containing ultrasound contrast agents on May 13, 2008, concerns still exist regarding the safety of these compounds, particularly in critically ill patients. A retrospective analysis was performed using the Premier Perspective Database.

To view this study, please [click here](#)



Large analysis suggests echo contrast agents associated with reduced mortality

Compared with patients not receiving a contrast agent, administration of perflutren lipid microsphere (PLM) injectable suspension contrast agent during echocardiography was associated with a 24 percent decreased risk of mortality, according to a retrospective analysis in the December issue of the *American Journal of Cardiology*.

To read this article, please [click here](#)



The FDA's Cardiovascular and Renal Drugs Advisory Committee recently held a briefing on the New Drug Application for Imagify™

The Advisory Committee demonstrated concern that the safety risks associated with the use of this microbubble ultrasound contrast agent are inappropriate for the proposed clinical use of Imagify.

To view the FDA's Briefing Document, please [click here](#)



Definity Secured 24 Percent of the Echocardiography Market Share for Enhanced Procedures in October 2008 Despite Being Added to the FDA Safety Issue List

"The gain in market share for Definity and Optison may be related to the recent formation of the **International Contrast Ultrasound Society (ICUS)**," stated Anna Fisher, analyst at AMR. "The ICUS was formed in September of this year in light of all the FDA black box warnings in the contrast ultrasound market. The Society's goal is to enhance the understanding of the effectiveness and safety of contrast ultrasound agents for cardiac and abdominal imaging."

To read this article, please [click here](#)



Safety and Risk–Benefit Profile of Microbubble Contrast Agents in Echocardiography

The 'Boxed Warning' disease state contraindications and mandated 30-minute monitoring period issued by the FDA in October 2007 had a chilling effect on ultrasound contrast agent use in the US. [This paper](#) looks at the safety and risk-benefit of these agents in echocardiography



Safety and Efficacy of Commercially Available Ultrasound Contrast Agents for Rest and Stress Echocardiography

The Food and Drug Administration recently placed a "black box" warning on the ultrasound contrast agents Definity (Bristol-Myers Squibb Medical Imaging, Billerica, Massachusetts) and Optison (GE Healthcare, Princeton, New Jersey)

This study seeks to define the risks versus benefits of ultrasound contrast agents in patients undergoing stress echocardiography.

To view this study, please [click here](#)

US Radiology

Microbubble Contrast Agents for Ultrasound Imaging — Safety and Efficacy in Abdominal and Vascular Imaging

The use of contrast ultrasound for abdominal and vascular imaging is widely approved outside the US, and offers excellent diagnostic capabilities, safely, for multiple indications. [This article](#) provides a summary of CEUS use in liver and other abdominal imaging.



The Safety of Definity and Optison for Ultrasound Image Enhancement: A Retrospective Analysis of 78,383 Administered Contrast Doses

Because of post-marketing surveillance reports of 4 patient deaths that may have been temporally related to the administration of perflutren containing ultrasound contrast agents, the US Food and Drug Administration (FDA) issued a “black box” warning for Definity (Lantheus Medical Imaging, North Billerica, MA) and Optison (GE Healthcare, Buckinghamshire, UK) on October 12, 2007.

The purpose of this retrospective analysis was to define the incidence of severe adverse events after exposure to ultrasound contrast agents

To view this analysis, please [click here](#)

US Radiology

Cardiovascular Applications of Ultrasound Contrast Agents

Since the first described use of ultrasound contrast, 40 years ago, the advances in this technology have demonstrated improved visualization in echocardiography across a variety of clinical scenarios. [This paper](#) reviews the applications and benefits of continued and expanded use of contrast echocardiography



Contrast-enhanced Transvaginal Sonography of Benign and Malignant Ovarian Masses”

This prospective study describes the preliminary experience (23 masses) with this technique -- which found significant differences in peak enhancement, wash out and vascular volume in the two groups. This has significant potential application in the early detection of ovarian cancer.

The full report of this study is available [here](#)
Video clips are also available [here](#)



Left ventricular volume measurement with echocardiography: a comparison of left ventricular opacification, three-dimensional echocardiography, or both with magnetic resonance imaging.

Both contrast enhanced (CE) two-dimensional echocardiography (2DE) and three-dimensional echocardiography (3DE) have been proposed as techniques to improve the accuracy of left ventricular (LV) volume measurements. In a study of 50 patients with past myocardial infarction, we sought to examine the accuracy of non-contrast (NC) and CE-2DE and 3DE for calculation of LV volumes and ejection fraction (EF), relative to cardiac magnetic resonance imaging (MRI).

To view this study, please [click here](#)



Detection of coronary artery disease with perfusion stress echocardiography using a novel ultrasound imaging agent: two Phase 3 international trials in comparison with radionuclide perfusion imaging

To determine if perfusion stress echocardiography (PSE) with ImagifyTM (perflubutane polymer microspheres) is comparable to stress perfusion imaging using ^{99m}Tc single photon emission computed tomography (SPECT) for coronary artery disease (CAD) detection.

To view this study, please [click here](#)



JACC study shows no additional risk from echo contrast agents

By: Eric Barnes January 8, 2009

Despite recent safety warnings, ultrasound contrast agents are safe and effective for assessing patients during echocardiography, concludes a massive review of more than 42,000 patients examined at three institutions in the U.S.

The retrospective study, which appears in this month's Journal of the American College of Cardiology, found no significant differences in death rate or myocardial infarction (MI) between patients who received ultrasound contrast agents and those who did not during stress echocardiography.

In 2007, the U.S. Food and Drug Administration (FDA) mandated the placement of a black box warning for ultrasound contrast agents Definity from Lantheus Medical Imaging (North Billerica, MA) and Optison from GE Healthcare (Chalfont St. Giles, U.K.), following reports of 11 deaths that occurred around the time of their administration.

The warning was modified in July 2008 to exclude only the most unstable patients from use of the agents. However, many institutions had long since stopped using echo contrast, a product that proponents believe significantly improves the quality of many exams that would otherwise be unreadable.

Echo contrast's utility was highlighted in this month's JACC article, authored by Dr. Melda Dolan, from Saint Louis University Hospital in Missouri, as well as colleagues from University of Nebraska Medical Center in Omaha and the Mayo Clinic in Rochester, MN (JACC, January 2009, Vol. 53, pp. 32-38).

To read the article, click [here](#)

ASE American Society of Echocardiography

The American Society of Echocardiography (ASE) recently issued a consensus statement on the use of contrast agents, used to enhance echocardiogram images, and provided a guide for physicians who may be hesitant to use the contrast agents following a 2007 Food and Drug Administration (FDA) black box warning.

To view ASE's contrast agent guidelines click [here](#)

REIMBURSEMENT UPDATE

New CPT codes covering the use of ultrasound contrast agents during certain stress echocardiograms are effective in the United States as of January 1, 2009. For additional information, please visit the American Society of Echocardiography's website at:

<http://www.asecho.org/i4a/pages/index.cfm?pageid=3303>



**Bracco Group recently became a
Bronze-level founding sponsor of ICUS**

To inquire about ICUS sponsorship opportunities,
please contact [Mike Main](#), Treasurer at
info@icus-society.com

Save the date:



**ICUS Bubble
Conference 2009**

**Advances in
Contrast Ultrasound**

October 21 - 23, 2009

Chicago, IL

www.bubbleconference.com

Global Interest in ICUS Continues

Since the launch of the International Contrast Ultrasound Society (ICUS) on September 17, 2008, the requests for membership have created a truly international organization.

To date, ICUS has recruited medical professionals in the following 26 countries:

Australia	Greece	Norway
Brazil	Hong Kong	Poland
Canada	India	Romania
China	Israel	Spain
Cyprus	Italy	Switzerland
Denmark	Japan	Turkey
Egypt	Korea	United Kingdom
France	Mexico	USA
Germany	Netherlands	

For more information on ICUS membership, please visit [ICUS Society Membership](#)

ICUS MISSION

- To promote the safe and efficacious use of contrast-enhanced ultrasound (“CEUS”) in patients with diverse medical profiles and disease states.
- To provide a global inter-disciplinary forum to foster education, research, and development of CEUS applications.
- To facilitate open and dynamic communications among medical professionals and scientists in the fields of cardiology, radiology, gastro-intestinal medicine, vascular medicine, internal medicine, hepatology, and other medical specialties and basic science disciplines.
- To foster education of the public on the safe and efficacious use of CEUS in patients.
- To create awareness in the medical community about the clinical benefits of CEUS.
- To sponsor a website and an annual international conference that will foster global inter-disciplinary education, research and development of clinical ultrasound and contrast ultrasound applications

Send us your news at info@icus-society.org

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