The Sensitivity and Specificity of Whisper®

Sensitivity and specificity are important measures of any diagnostic or screening test. Whisper's method of lung disease detection represents a novel approach in the animal feedlot industry. The uniqueness of this disease management approach raises the issue of how best to evaluate a technology that doesn't have a historical presence or a methodologically comparable product or device. Whisper® is charting new territory in disease management strategy and ultimately in feedlot practice culture. Defining success metrics is paramount to having meaningful dialogue on how well Whisper® is performing. By determining the best measures to assess Whisper's sensitivities and specificities, we will gain a reference point to begin new discussions and advance our understanding of Whisper's impact in the industry.

Whisper® and Acoustic Signatures

Whisper® incorporates recorded auscultation sounds into a digitized computer analysis algorithm to determine disease status – giving both qualitative and quantitative results indicators. Whisper® makes its assessment solely on the basis of lung sounds. In other words, it can detect the acoustic signature of disease when auscultation reveals lung sounds that are pathognomonic for lung disease. For the purpose of these discussions we will limit the context to the categories of either the 'presence' or 'absence' of lung disease and not involve severity level assessments.

Sensitivity

The sensitivity of a diagnostic test is determined by how well the test identifies all cases where a disease or condition is present. (See Table 1.) The sensitivity of Whisper® is addressing the following question: *Can Whisper® identify all animals that have an acoustic signature of lung disease?* The concern is: *will Whisper® misdiagnose any sick animals as healthy?*

		Acoustic Signature of Disease		
		Present	Absent	
Gold Standard Test	Sick	*True Positive*	False Negative	[True Positives] / [True Positives + False Negatives] = Sensitivity
	Healthy	False Positive	*True Negative*	[True Negatives] / [True Negatives + False Positives] = Specificity

Table 1. Definitions of Sensitivity and Specificity.

An important question that must be ascertained is whether or not there is a "gold standard" for lung disease detection? In published literature review, we find that nearly 40% of all cattle with lung lesions present at harvest were never diagnosed or treated for lung disease using current screening protocols. Also, some 40% of those animals treated for lung disease were without lesions at harvest. (See Figure 1.) This would suggest widespread misdiagnosis if we agree that lung lesions equate to lung disease. The literature also points out that mortality rates

are on the rise for respiratory illness while declining for other illnesses.
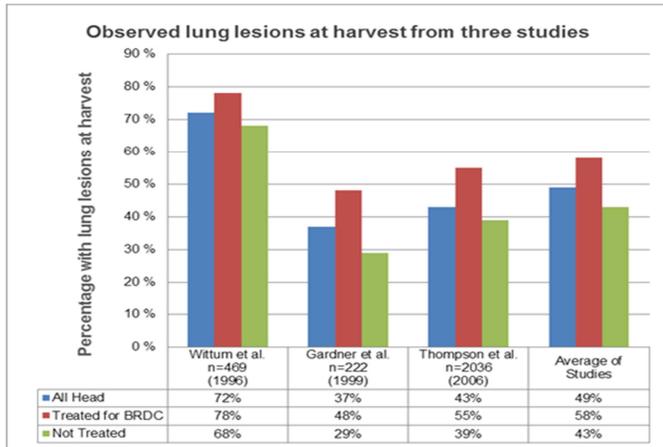

Figure 1. Lung lesions at harvest studies.

Researchers and industry experts all agree that lung disease is the number one cause of feedlot morbidity and responsible for up to 55% of feedlot mortality.   Thus, feedlot respiratory illness isn't waning as a major concern and furthermore the industry is missing a lot of lung disease detection on the basis of lung lesions found at harvest.   Current respiratory illness detection methods are clearly failing to effectively manage and contain these illnesses. Auscultation's ability to screen for respiratory illness hasn't been formally evaluated in the feedlot setting. The current protocols for illness surveillance provide no data on auscultation as a screening tool because auscultation is usually employed after an animal has already been pulled and diagnosed as being ill.   This presents a challenge in determining the sensitivity of auscultation as a diagnostic or screening tool as Whisper® is an auscultation test.   Post mortem studies will approximate lifetime prevalence of lung disease, but not validate whether or not the lung disease produced changes to the lung sounds under auscultation. This would (somewhat) disqualify post mortem examination as a gold standard for disease detection via auscultation. It's hard to declare what constitutes a 'false negative' given based on auscultation given current research findings. That is, we don't know if all lesions elicit acoustic signatures of disease. Thus for Whisper®, the diagnostic and screening sensitivity is best determined as a function of agreement with expert feedlot auscultators who can validate the acoustic presentation of each animal. Currently there are studies underway looking at the agreement between Whisper® and expert auscultators.

Specificity

The specificity of a diagnostic test is determined by how well the test identifies all cases where a disease or condition is **not** present. (See Table 1.)   Specificity is addressing the following question: *Can Whisper® determine when an acoustic signature of lung disease is not present?* The concern is: *will Whisper® misdiagnose any healthy animals as sick?*

Geissler Corporation, L.L.C., and Production Animal Consultants, L.L.C, ran a pilot study on Whisper® whereby auscultation test results were compared to post mortem necropsy and

histopathology examinations. A paper is being submitted for publication. The results did indicate that when Whisper® detected lung sounds indicative of disease, lesions were found post mortem. No 'false positives' based on histopathology as a measure. While we don't know if all lesions produce acoustic signatures [the sensitivity question with false negatives] we can likely agree that where there's an acoustic signature of disease, there should be a lesion. If not, this would constitute a 'false positive' error. Thus, a post mortem study may lend itself to be more appropriate in a specificity analysis than a sensitivity analysis. When Whisper® didn't detect sounds of disease; post mortem studies were negative for histopathologic characteristics – thus correctly identifying 'true negatives.' These results support specificity.

Conclusion

In conclusion, it would appear that the most appropriate method to determine Whisper's sensitivity and specificity would be to compare Whisper® with expert feedlot auscultators as Whisper® is an auscultation test that detects acoustic signatures of lung disease. Whisper's innovative and unprecedented approach to disease management will likely be in a category of its own, defining new metrics. Ultimately, its value will be measured on the basis of feedlot disease management outcomes.