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S_{pCO}: Let's Not Throw the Baby Out With the Bath Water—Reply

In reply:

We thank Dr McEvoy for his thoughtful reply to our report. He is correct that our definition of false positive was restrictive; however, we based this definition on the manufacturer's stated accuracy specification, and, indeed, found that the RAD-57 functioned as specified. When broadened to include 2 standard deviations (95% of the data), the accuracy range would be ± 6%, a range that is challenging for the purpose of diagnosing CO poisoning.

We readily acknowledge that technician technique may play a role in obtaining accurate data, even though our technicians and study team were trained by the manufacturer on probe placement. Our concern is that, whether by technical limitations or operator error, the RAD-57 may provide an erroneously low S_{pCO} measurement in a patient with CO poisoning. We agree that S_{pCO} technology can be valuable in broadly screening for occult CO poisoning. We offer that an elevated S_{pCO} should raise concern about CO poisoning, especially if the evaluating clinician has not considered CO exposure. However, we strongly caution against using S_{pCO} measurement to rule out CO poisoning when symptoms and circumstances suggest it. Returning a misdiagnosed patient to the scene of the poisoning can have devastating and even deadly consequences.

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S_{pCO}: Let's Not Throw the Baby Out With the Bath Water—Reply

In reply:

The study by Weaver and colleagues[1] demonstrated that, while the RAD-57 CO-oximeter operated within the manufacturer's specifications, with 68% of S_{pCO} measurements falling within ± 3% of the laboratory carboxyhemoglobin (COHb) measurements of < 40%, in several cases the S_{pCO} reported by the RAD-57 underestimated the COHb. This raises concerns about the utility of the RAD-57 in identifying cases of occult CO poisoning, which is one of the primary potential benefits of a point-of-care noninvasive carboxyhemoglobin screening test. Furthermore, Weaver et al's findings were consistent with other studies of the RAD-57.[2-4]

In response to Weaver et al's study, Dr McEvoy opines that these failures of the RAD-57 to report a S_{pCO} consistent with the laboratory COHb measurement could have been due to technician technique. The concern has previously been raised by another industry representative,[5] in response to a prospective study that demonstrated wide limits of agreement and poor sensitivity of the RAD-57.[2] While technique may have been a contributor to the discrepancy between S_{pCO} and COHb in Weaver et al's study, this does not excuse the failure of the RAD-57 to identify elevated COHb levels. The use of any medical device is not isolated from user technique or user error, and dismissing false negative results described by Weaver et al and others as being due to poor technique ignores the potential consequences of broadening the clinical use of the RAD-57. If false negative values were obtained under relatively idealized settings (technicians were trained by industry representatives and were obtaining measurements in the setting of a research study), it is reasonable to assume that the rate of false negatives will not be lower in the non-idealized setting of real world clinical medicine, where attention to technique may be less meticulous than in a research study.

Given these considerations, the poor sensitivity, rate of false negatives, and the inaccuracy of the RAD-57 should be a warning to medical personnel that S_{pCO} is not definitive, and that a normal S_{pCO} should not be reassuring. Ultimately, the false negatives obtained by the RAD-57, whether due to technician technique, intrinsic device inaccuracies, or patient-level factors, demonstrates that the RAD-57 is not suitable as a screening device and that there is potential for measurement inaccuracies and patient harm in real world clinical settings.

We agree that further work to develop an accurate, precise, user-friendly, and non-invasive S_{pCO} monitor is warranted, and that a rapid, accurate, point-of-care carbon monoxide monitor would be extremely valuable. The RAD-57 monitor, however, does not meet these criteria, based on the available clinical data, and there is insufficient evidence for its broad clinical use.[1-4]

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The authors have disclosed no conflicts of interest.

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