

Commentary on: Sterling K. The rate of dissipation of mouth alcohol in alcohol positive subjects. *J Forensic Sci* 2012. In press. DOI: 10.1111/j.1556-4029.2011.02023.x

Sir,

The Sterling paper you recently published was disappointingly below the standards one would expect from your Journal. It is my understanding that this paper went through the peer review process.

I have detailed some of the problems with the paper below.

1. The whole purpose of the study was to compare the effects of contaminating residual mouth ethanol to an already existing blood ethanol concentration.
 - a. The pharmacokinetic status of the subjects was not determined in the study. Blood ethanol concentrations in a given subject are variable, nonuniform, discontinuous, and unpredictable during the absorption phase of ethanol kinetics. That condition provides for a very large confounder in the Sterling paper experiment. It is acknowledged by the author as well.
 - b. As the pharmacokinetic status of the subjects was not determined during the study, that confounder by itself is potentially so large as to make any results and conclusions in the Sterling paper forensically unreliable.
 - c. The author's own data described a paradoxical event with the breath result increasing instead of decreasing with two subjects, and incredibly, they do not discuss the pharmacokinetic confounder as a possible cause.
2. The study design is not randomized for subject assignment of treatment groups. This fault is due, at least, to the lack of a placebo control group. Randomization is one of the most important study design criteria necessary to increase the strength of the study results.
3. The study design is not controlled.
 - a. At least the subjects should have provided negative-control breath samples before and after oral exposure to the water used in the testing. There is no way to determine whether any of the subjects were providing breath samples contaminated with endogenous volatile organic compounds that caused an interference with the breath testing device or whether the water used contained any volatile organic compounds that caused an interference with the breath testing device.
 - b. The lack of a negative control in the study design by itself makes the results and conclusions forensically unreliable.
4. The study design does not describe subject inclusion criteria (if any). There is no description of any medical screening or medication screening or other requirements.
5. The study design does not describe subject exclusion criteria (if any). Therefore, it is unknown whether the subject population was homogenous or not.
6. Importantly, there are no inclusion or exclusion criteria regarding the oral health of the subjects, specifically concerning the

- presence or absence of extensive dental work, bridges, plates, dentures, or other structural anomalies of the oropharynx, all of which represent potential confounders in this study.
7. The volume of ethanol used for contamination of the oropharynx of each subject was not controlled. That by itself makes the results and conclusions forensically unreliable.
 8. The duration of ethanol exposure in the oropharynx of each subject was not controlled. That by itself makes the results and conclusions forensically unreliable.
 9. The method of ethanol contamination of the oropharynx of each subject was not specified. That is another uncontrolled variable that makes the results and conclusions forensically unreliable.
 10. It appears that the author misunderstands and misapplies the medical term gastric regurgitation as applied to the contamination of a breath ethanol sample.
 - a. Gastric regurgitation includes "the casting up of incompletely digested food," commonly known as vomiting. Gastric regurgitation is an unlikely and rare event in the breath ethanol testing arena.
 - b. And it is not believable as the author suggests that a possible mechanism of mouth ethanol contamination in this study (or any other study) is by "regurgitation before each test."
 - c. Gastric reflux is the retrograde movement of solids, liquids, and gases from the stomach up the esophagus. Gastric reflux of stomach gases is a very common event, often silent and unnoticed by the person experiencing it, and often undetected by nearby observers. This is the more common mechanism of contamination of a breath sample from gastric contents.
 11. Contamination of a breath sample by the presence of residual mouth alcohol is a completely different mechanism of contamination.
 - a. Ethanol may remain in the oropharynx for a variable period of time after the conclusion of a drinking episode. The reasons include anatomic variation and anomalies of the oropharynx, dental abnormalities, bridges, dentures, and others.
 - b. The origin of the ethanol is from the ethanol beverage(s) consumed, not from the gastric contents.
 12. As a result of the poor study design and obvious fatal flaws in methodology, the Sterling paper cannot be relied upon for its data or conclusions.

Okorie Okorocho,¹ B.A., J.D.
¹Toxicology Expert Witness,
117 East Colorado Blvd, Suite 465,
Pasadena, CA 91105.
E-mail: okorie@gmail.com