

Concerns raised about variable performance of some UK personal use breathalysers

Ability of devices to detect potentially unsafe alcohol levels prompts questions about regulatory process

[Diagnostic accuracy study of three alcohol breathalysers marketed for sale to the public doi 10.1136/bmjopen-2014-005811]

The ability of some breathalysers widely sold to the UK public to detect potentially unsafe levels of breath alcohol for driving, varies considerably, reveals research published in the online journal *BMJ Open*.

The findings call into question the regulatory process for approving these sorts of devices for personal use, say the researchers, particularly as false reassurance about a person's safety to drive could have potentially catastrophic consequences.

The researchers compared the diagnostic accuracy (sensitivity) of three personal use breathalysers to detect alcohol levels at or over the UK legal limit in 208 adults, who were drinking in college bars and pubs in the centre of Oxford, England, in late 2012 and early 2013.

At least 20 minutes after drinking, participants were asked to test the single use Alcosense Single (100 people) or the comparable Dräger Alco-check (108 people), as well as the digital multi-use Alcosense Elite, one minute apart, in random order.

These devices are widely available in leading pharmacies and other major retailers, as well as online.

The participants, whose average age was 20, estimated that they had drunk an average of 6 units of alcohol (46 g) that evening, ranging from 1 to 25 units (8-204 g).

The readings from the three devices were compared with those obtained from a Dräger Alcotest 6510 device, which is used by the police to check drivers' legal alcohol limits at the roadside.

The legal limit for driving in the UK is 35 ug/100 ml of breath alcohol, and almost one in five (18%; 35) of those tested were at or over this limit, when the police breathalyser was used.

Compared with the police breathalyser, the digital Alcosense Elite had a sensitivity of around 90%, while the Dräger AlcoCheck had a sensitivity of just under 95%, in the main analysis.

But even a sensitivity of 95% means that around 1 in 20 people over the legal driving limit for alcohol would be falsely reassured, say the authors: "We question whether even this would be sufficient sensitivity to assess safety to drive," they write.

And the Alcosense Single had an even lower sensitivity of only 26%, compared with the police breathalyser, meaning that the device would pick up only around one in four people over the legal limit, shortly after drinking.

And when participants, rather than the researchers, interpreted the results of this device, the sensitivity fell further to 17%.

The researchers acknowledge that the study has limitations. For example, the manufacturers of the Alcosense Elite stipulate that it should be used 30 minutes after drinking, when it was used 20 minutes afterwards in this study, so this may have affected the results for this breathalyser.

And the profile of the drinkers in the study may not be typical of those who are likely to buy breathalysers for personal use, they add. Similarly, the researchers didn't test the accuracy of the devices when used the day after drinking.

But they say: "Our research suggests that at least some personal breathalysers available for sale to the public are not always sufficiently sensitive to test safety to drive after drinking alcohol, where use of inaccurate information from breathalysers, thought to be accurate, could have catastrophic safety implications for drivers."

They add: "The fact that these devices are sold in well-established pharmacies, including national chains, does not guarantee sufficient accuracy for safe use."

Furthermore, regulatory approval, signified by the CE or NF markings, doesn't appear to have anything to do with accuracy, raising wider questions about how these markings may be perceived by consumers, they point out.

"Our research raises worrying questions about the level of scrutiny that medical tests intended for sale to the public undergo in Europe, and raises wider concerns about how diagnostic accuracy, in particular, is evaluated," they conclude.