



A clinical investigation into the ability of subjects with a lung disease to provide breath specimens using the Dräger 6510

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ABSTRACT

In the enforcement of drink driving laws failing to provide a breath specimen for alcohol analysis at the roadside when requested by a Police Officer is an offence in many countries. Some drivers claim that a lung disease prevented their ability to be successful. This study aims to investigate the relationship between the presence of a lung disease and the ability to provide a successful breath specimen using the Dräger 6510 screening device. Sixty participants with lung disease and nineteen control participants underwent pulmonary function tests and were then tested with a Dräger 6510 screening device. Only one participant was unsuccessful using the Dräger 6510, this participant suffered from interstitial lung disease. The pulmonary function test results did not indicate if someone would be successful or how many attempts would be needed to be successful. The presence of a lung disease did not indicate if a driver would be unsuccessful however all participants were free from infection and the participants with a lung disease were stable at the time of testing. Correct instruction, subject cooperation and the technique used by the driver to provide a breath specimen were found to be important factors in the success of a breath test.

1. Introduction

In the Republic of Ireland and also many other jurisdictions worldwide a driver may be requested to provide a roadside or screening breath specimen at a Mandatory Intoxicant/Alcohol Testing (MIT/MAT) checkpoint, following a road traffic crash or if a Police Officer suspects that the driver may be under the influence of alcohol. If the roadside test is positive, the driver is arrested and brought to a Police Station. At a Police Station the driver may be requested to provide two acceptable breath specimens into an Evidential Breath Testing instrument. The outcome of the evidential breath test in the Police Station is produced to the Court as evidence that an offence may have been committed under the Road Traffic Act.¹ It is an offence under the Road Traffic Act to refuse or fail to provide a breath specimen for alcohol analysis when requested by a Police Officer either at the roadside or in a Police Station. The Irish Road Traffic Act does not distinguish between drivers that simply refuse to supply a breath specimen and those who attempt but are not

physically able and consequently fail to provide a breath specimen, however section 22 of the Road Traffic Act 2010¹ allows for a “special or substantial reason for his or her failure”, in other words a medical condition that may affect a drivers’ ability to provide a breath specimen.

The need for this study has arisen from court cases in relation to drivers failing to provide a breath specimen for alcohol analysis under the Road Traffic Act and claiming at a later date that impaired lung function affected their ability to provide an acceptable breath specimen. Respiratory physicians and family doctors have, on occasion, been tasked with assessing their patient driver’s ability to provide such breath specimens on a date well after the date of the arrest. The aim of this study is to provide more information for the Court and medical practitioners to assist in dealing with “failure to provide” (FTP) cases.

The Dräger 6510 screening device was approved by the Medical Bureau of Road Safety (MBRS) and introduced in the Republic of Ireland in 2004, for roadside breath testing. It uses fuel cell technology to determine the presence of alcohol in the breath. The driver is required to

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supply a continuous breath specimen for at least 2 s at approximately 13 L/min to trigger the device and when the flow rate drops to approximately 10 L/min the device will sample the breath specimen. The driver needs to provide a volume of at least 1.2 L. The mouthpiece is designed to provide minimal back pressure. If a driver cannot provide a successful breath specimen, they may be charged with “failure or refusal to provide”.

Previous studies were carried out in other countries with similar equipment but none using the Dräger 6510 screening device. The study protocol is similar to that of Honeybourne et al.^{2,3} These studies were carried out in the U.K. using the Lion Intoxilyzer® 6000UK² and the screening device, the Lion Alcolmeter® SL-400.³ Honeybourne found the consumption of alcohol did not affect a participant’s ability to successfully provide a breath specimen²; therefore, none of the participants in this study were given alcohol.

An overall failure rate of 22.5% (using the Lion Alcolmeter® SL-400) was reported by Honeybourne, whose study groups included patients suffering from asthma, chronic obstructive pulmonary disease (COPD) and restricted lung disease.³ That device has a minimum flow rate of 25L/min. Crockett et al.⁴ tested subjects with a variety of pulmonary disorders and had a failure rate of 15.7% using the Lion Alcolmeter® SD-400. The majority of the subjects (86.5%) who failed to provide in that study were female. The minimum flow rate was found to be approximately 19.6L/min for the Lion Alcolmeter® SD-400 screening device. The Dräger 6510 has lower blowing requirements than both these devices so the failure rates were expected to be lower compared to those two studies.

The aims of this study were:

- To assess the ability of a person with a lung disease to provide a breath specimen using a roadside breath alcohol screening device.
- To investigate the relationship between the presence of a lung disease and the ability to provide a successful breath specimen under the Road Traffic Act using a roadside breath alcohol screening device.

2. Method

Participants with lung diseases were recruited from the outpatient clinic of the pulmonary laboratory in St Vincent’s University Hospital (SVUH), Dublin. They were attending the pulmonary laboratory as part of their routine care and had to meet criteria for inclusion in the study: (i) diagnosis with a single pathology, (ii) no infection or change in medication and (iii) no alcohol detected in their system (N = 64).

A control group was also recruited from volunteers in University College Dublin (UCD). The control group had (i) no diagnosed lung disease, (ii) no current respiratory infection and (iii) no alcohol in their system. The control group was age and sex-matched to the study participants as far as was practicable (N = 20). All testing on controls was carried out in the MBRS, UCD.

Full ethical approval was given by SVUH and UCD Ethics Committees. Each participant was required to sign a letter of consent before participating. Details of the study were explained to each participant before participation. Patients with three different lung diseases were studied in addition to the control group. Each group contained up to 21 participants. The lung disease groups were categorised by a medical doctor according to “Interpretive strategies for lung function tests”⁵ for patients suffering from COPD, asthma and interstitial lung disease (ILD). Each participant with a lung disease was graded by a medical doctor with a level of severity; mild, moderate or severe. The entire control group was graded as normal. For COPD participants, their severity was graded using the Pulmonary Function Test (PFT); Forced Expiratory Volume in 1 s (FEV₁) percentage predicted results according to Global initiative for chronic Obstructive Lung Disease (GOLD)⁶ spirometry stages, see Table 1. Asthma severity was graded using the Global Initiative for Asthma (GINA)⁷ steps, that are based on how much

medication the participants were prescribed. For participants with ILD, their severity was diagnosed using the Diffusing capacity of the Lungs for Carbon monoxide (DLCO) percentage predicted result. If a DLCO result was not available, the Forced Vital Capacity (FVC) percentage predicted result was used.

On arrival at the pulmonary laboratory in SVUH, PFT tests (FVC, FEV₁ and DLCO) were carried out on each participant as part of their scheduled routine care. Participants were requested not to take any inhalers before they attended the pulmonary laboratory as reversibility tests using a bronchodilator (Salbutamol) were included as part of the standard medical suite of tests. The FVC and FEV₁ tests were carried out before and after the administering of the bronchodilator. Forced Expiratory Ratio (FEV₁/FVC) was also calculated from all the FEV₁ and the FVC results for each participant. DLCO was also corrected for haemoglobin and reported as DLCOc. The control group was not given a bronchodilator, consequently there is only one set of results for each PFT test. The control group also did not carry out the DLCO PFT test. All lung function test results were recorded by hospital staff and for the lung disease groups their results were retained in the patient’s medical file. All data was anonymised, and a unique I.D. number was assigned to each participant. The spirometry guidelines used by the hospital staff were “Standardisation of Spirometry” by Miller et al.⁸ The results of FVC, FEV₁ and DLCO tests were recorded as percentage predicted of a normal population according to Quanjer et al.,⁹ this was calculated automatically by the spirometry equipment. The PFT equipment used in the hospital pulmonary laboratory included the MasterScreen PFT and Body Plethysmography systems from Carefusion which both utilise Sentry suite V2.17 software. In the MBRS, for the control group, a Vivavysis Microlab desktop spirometer with V2.36 software was used to carry out the PFT tests.

On completion of the PFT tests, participants were asked to provide one successful breath specimen using a Dräger 6510 while seated. All breath tests were carried out by MBRS staff. While the legislation is silent on the number of attempts a driver may make to provide a roadside breath specimen, for the purposes of this study a failure to provide was recorded if the patient was unable to provide an acceptable breath specimen after three attempts. If a participant was found to have had alcohol in their system at this stage, they would have been excluded from the study.

The number of subjects who failed to provide a successful specimen and the number of attempts it took to provide were recorded. The operator of the screening device also made note of any relevant observations or comments by the participant. The instructions given to the participants by the operator of the breath testing equipment were consistent with the instructions a Police Officer gives to drivers. The instructions are “Take a deep breath. Make a seal with your lips around the mouthpiece. Blow at a steady rate until I tell you to stop.” Additional instructions and demonstrations were given in some cases where the participant did not understand the technique correctly. A Police Officer is advised to explain what is required of a driver in plain terms and is not restricted to the above instructions or a legal explanation.

Data analysis was carried out using SPSS version 24. A significance

Table 1
Severity grading for each lung disease group.

Diagnostic Test	Grading			Lung Disease Group
	Mild	Moderate	Severe	
FEV ₁ % Predicted	>80	50–80	<50	COPD
GOLD STAGE	STAGE 1	STAGE 2	STAGE 3/4	COPD
GINA Step no.	Step 1 & 2	Step 3	Step 4 & 5	ASTHMA
DLCO % Predicted	60–80	40–60	<40	ILD
FVC% Predicted	>70	50–70	<50	ILD

level of $p < 0.05$ was used. Normality tests (Shapiro-Wilk) were carried out on each variable, if $p < 0.05$ then the data was classified as not normally distributed, if $p > 0.05$ then the data was classified as normally distributed. For data that was not normally distributed non-parametric tests (Wilcoxon signed, Kruskal-Wallis, Fisher's Exact) were used to compare differences, data that was normally distributed parametric tests (t-tests, ANOVA) were used.

3. Results

In total 84 participants were tested for this study. Five of the participants' results could not be used in data analysis for various reasons. Two participants (one COPD group, one undiagnosed) were excluded due to suffering from bronchitis on the day of testing. One participant was excluded due to a dual diagnosis of two disorders. One participant from the asthma group was excluded due to ethnicity, the spirometry equipment was pre-programmed to calculate percentage predicted values for Caucasians only according to Quanjer et al.⁹ and as this participant was non-Caucasian their predicted results would not be reliable. One of the controls was also excluded due to borderline normal results in conjunction with a childhood history of asthma. No participants were excluded due to alcohol in their system. Data analysis was carried out on a total of 79 participants. The breakdown of the age, BMI, PFT results, gender, and the number of attempts made is shown in Table 2.

3.1. Dräger results

The overall failure rate is 1.3%, no participant in the control group failed to provide a breath specimen. Only one participant in the lung disease groups failed to provide a breath specimen, this participant was in the ILD participant group with moderate severity. This participant was female, a non-smoker and was 61 years old. The mean age of successful participants was 61.5 years which is approximately the age of the one unsuccessful participant. The distribution of ages of the participants

was found not to have a significant difference between the numbers of attempts made by the participants (Kruskal-Wallis test, $p = 0.988$). The mean BMI of all participants was 26.5, the unsuccessful participant had a BMI of 31.7, see Table 2 for the range of BMI's. The distribution of the participants BMI was found not to have a significant difference between the numbers of attempts made (Kruskal-Wallis test, $p = 0.770$). There was no significant difference found between the number of attempts made by male and female participants (Fisher's Exact test, $p = 0.136$).

In this study 87.3% (69/79) of participants were successful on the first attempt, 7.6% took two attempts to provide a sufficient specimen and 5.1% took the maximum allowed three attempts. Table 2 shows the breakdown of the number of attempts made by participants for each group. For the one unsuccessful participant all three attempts were deemed insufficient by the screening device. The proportion of participants successful on their first attempt was similar across the three lung disease groups; all the controls needed only one attempt to be successful. No significant difference was found between the number of attempts made by each participant group (Fisher's Exact test, $p = 0.452$).

3.2. Pulmonary function test results

Participants with lung diseases ($N = 60$) were asked on the day of testing not to take an inhaler before attending the pulmonary laboratory in SVUH but eleven of them had taken an inhaler that day already therefore only data for post-reversibility was available. The control group ($N = 19$) was not administered with a bronchodilator so there is one set of pulmonary function test results available; this data was treated as equivalent to post-reversibility data as they had no underlying lung disease. From the available pre-reversibility PFT results ($N = 49$) significant differences were found between the means of the pre and post PFT results indicating the bronchodilator had a significant effect on the lung function of these participants (Paired t-test, FEV₁ and FVC; $p < 0.05$). The means of each PFT test increased after the participant took a bronchodilator. For FEV₁/FVC a significant difference was also found between pre-and post-reversibility (Wilcoxon signed test, $p < 0.05$), the

Table 2
Mean, standard deviation (sd) and range of age, BMI and PFT results, gender breakdown and no. of attempts made by participants.

VARIABLES	ASTHMA (n = 19)		COPD (n = 20)		ILD (n = 21)		CONTROL (n = 19)		OVERALL TOTAL (n = 79)	
	mean (sd)	range	mean (sd)	range	mean (sd)	range	mean (sd)	range	mean (sd)	range
Age(years)	55.1 (18.14)	22.8–82.1	67.9 (10.97)	35.4–83.2	63.4 (11.34)	39.3–83.4	58.9 (14.29)	29.9–72.3	61.5 (14.44)	22.8–83.4
BMI	$\frac{n = 18}{(4.54)}$ 26.1	20.0–40.0	$\frac{n = 19}{(5.61)}$ 27.3	16.0–39.0	27.5 (5.38)	19.0–40.6	24.8 (3.56)	20.0–31.1	$\frac{n = 77}{(4.88)}$ 26.5	16.0–40.6
FEV ₁ % Predicted (post)	90.9 (22.97)	34.1–129.0	$\frac{n = 18}{(25.15)}$ 68.0	34.0–105.4	84.4 (17.99)	53.0–113.0	108.8 (13.84)	87.0–136.0	$\frac{n = 77}{(24.60)}$ 88.2	34.0–136.0
FVC % Predicted (post)	107.7 (21.50)	70.6–155.0	$\frac{n = 18}{(18.71)}$ 99.5	58.0–128.0	89.7 (21.05)	57.0–126.0	113.1 (14.53)	89.0–134.0	$\frac{n = 77}{(20.89)}$ 102.2	57.0–155.0
FEV ₁ /FVC (post)	75.7 (14.48)	45.3–105.7	$\frac{n = 18}{(19.96)}$ 55.5	29.5–95.7	77.5 (11.17)	58.2–96.3	78.1 (6.48)	62.0–88.0	$\frac{n = 77}{(16.34)}$ 72.0	29.5–105.7
DLCO%	$\frac{n = 16}{(9.40)}$ 83.7	66.0–102.0	$\frac{n = 16}{(15.84)}$ 59.3	31.7–86.4	$\frac{n = 18}{(19.82)}$ 58.5	22.0–89.0	Not recorded		$\frac{n = 50}{(19.40)}$ 66.8	22.0–102.0
DLCOc %	$\frac{n = 17}{(9.11)}$ 81.0	64.0–96.1	$\frac{n = 15}{(18.53)}$ 62.1	31.5–92.4	$\frac{n = 18}{(19.64)}$ 59.0	24.0–96.0	Not recorded		$\frac{n = 50}{(18.91)}$ 67.4	24.0–96.1
Gender	No. of participants		No. of participants		No. of participants		No. of participants		No. of participants	
Male	7		10		13		10		40	
Female	12		10		8		9		39	
Dräger No. of Attempts	No. of participants		No. of participants		No. of participants		No. of participants		No. of participants	
1	15		18		17		19		69	
2	3		1		2		0		6	
3	1		1		2		0		4	

median results also increased post-reversibility.

While lung disease participants were diagnosed with differing levels of severity, the numbers were insufficient to draw any conclusions between the level of severity and the ability to provide a successful breath specimen.

Further data analysis was carried out on results from the PFT tests post-reversibility. Table 2 shows the mean, standard deviation and range of the results for FEV₁% predicted value, FVC % predicted value and FEV₁/FVC post-reversibility for each participant group and overall total. Two participants did not have reversibility carried out as their initial results were considered too variable by the physiologist and the effect of the bronchodilator may have been masked by that baseline variability. These two were excluded resulting in a total of 77 participants for further data analysis. These two excluded participants were successful in providing a breath specimen. After the administration of a bronchodilator the PFT results of the lung disease groups had significant differences compared to the control group (for FEV₁ and FVC; ANOVA test, both $p < 0.05$, for FEV₁/FVC; Kruskal-Wallis test, $p < 0.05$). The mean results of each PFT for the control group were higher than the mean of each lung disease group.

For the unsuccessful participant their FEV₁% predicted (post) result was 64% which is below both the overall mean (88.2%) and the mean of the ILD group (84.4%). This same pattern is seen for FVC % predicted (post), with a result of 63% (overall mean = 102.2% and ILD group mean = 89.7%). Only with FEV₁/FVC (post) does the unsuccessful participant have a result (86.7) greater than the overall mean (72.0) and the ILD group (77.5). The unsuccessful participant did not have the minimum or maximum result for any of the PFT results.

Figs. 1–3 shows the spread of each PFT result in relation to the number of attempts made by each participant. The one unsuccessful participant is marked by a black square. Considerable overlapping of PFT results can be seen between each group, the minimum and maximum results for each PFT test were in the group who were successful on their first attempt. No significant differences were found between each group of attempts for each PFT test (for FEV₁ and FVC; ANOVA test, $p = 0.583$ and $p = 0.062$ respectively, for FEV₁/FVC; Kruskal-Wallis test, $p = 0.771$).

The DLCO and DLCOc were measured for participants with impaired lung function only; the unsuccessful participant was unable to perform this test. Nine other participants had no results for DLCO and DLCOc, in the opinion of the physiologist this was due to their insufficient lung capacity or them not being able to perform the test correctly. The results for the DLCO and DLCOc can be seen in Table 2.

4. Discussion

The participants in this study had a wide range of ages, the gender

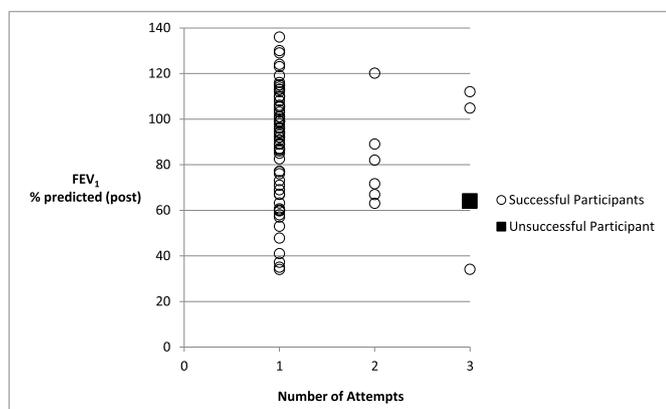


Fig. 1. FEV₁% predicted values post reversibility divided by the number of attempts made by each participant.

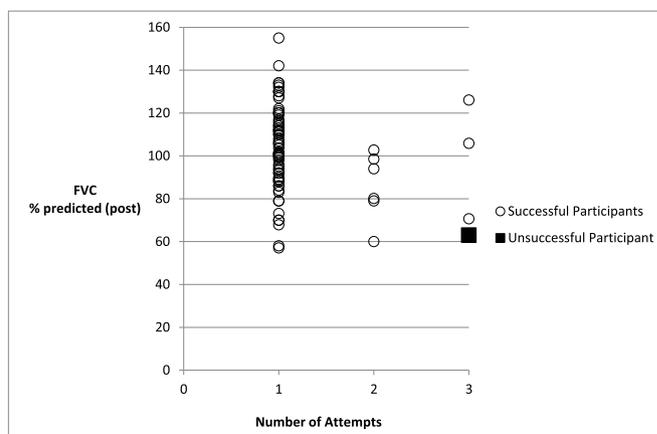


Fig. 2. FVC % predicted results post reversibility divided by the number of attempts made by each participant.

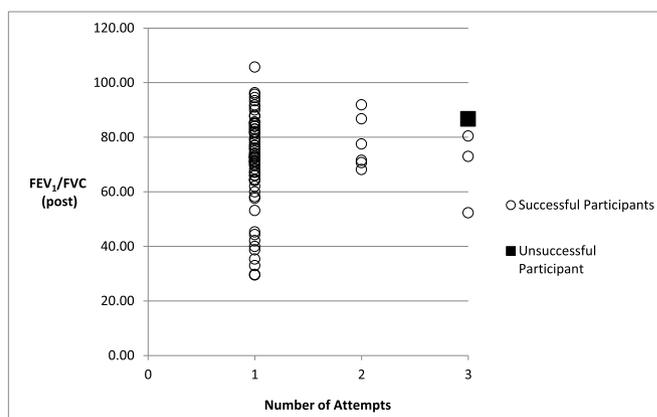


Fig. 3. FEV₁/FVC results post reversibility divided by the number of attempts made by each participant.

split was nearly even, and the lung disease groups suffered from various levels of severity. The overall success rate was 98.7%. All but one participant was able to successfully provide a breath specimen. Statistical analysis on participants' age, gender and BMI did not indicate the ability to provide a successful breath specimen. Successful participants included four male participants with severe COPD and one female participant with moderate COPD who is a smoker and has one lung.

With only one unsuccessful participant in the study it is not possible to establish if one PFT test could assist medical practitioners or the Courts to determine whether a driver with a lung disease could successfully provide a breath specimen at the roadside. The unsuccessful participant's PFT results were not the lowest or highest values when the overall results were examined. When the participants were separated into the number of attempts made (see Figs. 1–3), the unsuccessful participant has the lowest FVC result for all the participants that took three attempts. For the FEV₁/FVC ratio the unsuccessful participant had the highest result for that group. Overlapping of PFT results for successful and unsuccessful subjects have been found in previous studies.^{2–4} Honeybourne et al.³ found subjects with a FEV₁ less than 1.1 L may have difficulty in activating the Lion Alcolmeter® SL-400, but participants in that study with an FEV₁ greater than 1.1 L also failed to activate the screening device. No clear line or threshold can be established for particular PFT tests. Odell et al.¹⁰ found significant differences between unsuccessful and successful participants using the Lion Alcolmeter® SD2 for FEV₁, FVC and FEV₁/FVC but again there was overlap of results between each group. Both these devices have higher blowing requirements in terms of flow rate and minimum volume, so they are not

directly comparable to the Dräger 6510 results. The PFT results do not indicate if someone will be successful or how many attempts will be needed.

The minimum flow rate for the Dräger 6510 is substantially lower than any of the previous studies carried out with screening devices, this may explain why the failure to provide percentage rate of 1.3% is considerably lower compared to those studies.^{3,4,11} Since the Honey-bourne³ study in 1999 the flow rate requirements and minimum volumes for available breath screening devices have decreased, making it easier for people with lung diseases to successfully provide breath specimens as seen in this study. The Lion Alcolmeter® SL-400 and SD-400 both had higher flow rates of 25L/min³ and 19.6L/min⁴ respectively compared to a trigger flow rate of 13L/min for the Dräger 6510. Also, both the Alcolmeter devices required a minimum volume of 1.5 L, the Dräger 6510 requires 1.2 L. In this study participants were administered a bronchodilator before attempting to provide, this may also be a contributory factor to the low levels of FTPs reported here.

The MBRS, which is the body responsible under Irish road traffic law for the supply, approval and testing of all equipment for breath testing, has approved a new screening device-the Dräger 7510. The minimum trigger flow rate for this new device is 8L/min and sampling flow rate at 6L/min, it also needs a minimum volume of 1.2litres. When this device is introduced it should increase the number of drivers who are able to provide a breath specimen successfully at the roadside.

The entire control group required only one attempt to provide a breath specimen successfully. This suggests if a healthy person with no lung disease is required to provide a roadside breath specimen, they should be successful. No specific lung disease caused more difficulty in providing a successful breath specimen as seen from the consistent number of attempts made between each participant group. The number of attempts made between all groups was not significantly different therefore if a driver with a lung disease is taking their medication correctly, they should be successful in providing a breath at the roadside. From this study the presence of a lung disease does not indicate that a driver will be unable to provide a successful breath specimen using the Dräger 6510.

The operator of the screening device commented that the unsuccessful participant “did blow for quite a while but seemed to stop abruptly at each attempt”, causing the device to flag “Insufficient Volume” each time. As described in the Dräger 6510 Dual Limit instructions¹² this is flagged when the sampling volume is too low or if the subject is not blowing correctly e.g. abruptly stopping or sucking at the end of the breath sampling. The physiologist carrying out the PFT test reported that this participant was “unable to perform the DLCO” test; other participants also could not perform DLCO. There are common errors in performing DLCO e.g. inhalation too slow, stepwise inhalation or exhalation.¹³ Anecdotally, approximately 10% of pulmonary laboratory patients in SVUH have problems with performing spirometry correctly; similar failure rates have been reported in outpatient clinics in America according to Enright et al.¹⁴ This comprehensive review of approximately 18,000 outpatients attending the pulmonary laboratory at the Mayo Clinic in Rochester, MN was carried out to examine the within test session spirometry repeatability of adult outpatients. It reported that 90% of patients were able to reproduce FEV₁, FVC and Peak Expiratory Flow (PEF) results within the American Thoracic Society (ATS) standard limits.¹⁴ The techniques for providing a breath specimen into the Dräger 6510 and performing the PFT tests are different. Some of the PFT tests require the participant to blow as hard as they can and usually quite quickly compared to the screening device. Even though the screening device needs a relatively short breath provision it is designed to sample the end of a breath. This means it is looking for a drop in flow rate of the breath as if the subject is running out of breath. If a subject stops abruptly rather than naturally runs out of breath, then the device may flag “Insufficient volume” or “Blow interruption”. Some participants found it difficult to gauge the technique after just performing the PFT tests with which they would be more familiar as out-patients of the

pulmonary laboratory in SVUH. The control group who were unfamiliar with both techniques had no difficulty in succeeding on their first attempt.

Technique is an important factor in the success of providing a breath specimen. The operator’s understanding of the instructions and their importance are crucial to a successful breath test. The Irish legislation does not restrict the number of attempts that can be made for roadside breath testing, this study chose three attempts as a cut-off, however a Police Officer is free to offer the driver more if they feel it is needed. The one unsuccessful participant may have needed more attempts to master the technique. Female subjects have been found in other research studies to have more difficulty in providing successful specimens,⁴ this is most likely due to a smaller stature and therefore smaller lung volumes. As part of operator training for Police Officers in the use of breath testing devices this could be emphasised that female drivers, particularly elderly females, may have more difficulty. For general spirometry tests cooperation between the subject and the operator is required,⁸ as it is for breath specimens taken under the Road Traffic Act. This study used the instructions the Police Officers use as set out in the Methods section above, but they are not restricted to just these. If the operator feels they need to add more detail or to demonstrate themselves they are free to do this, for example a Police Officer may take a mouthpiece and show how to seal their lips around it and exhale to a driver. This will help in the success of the breath test. This is emphasised in training; however, the subject must be willing to cooperate and provide a genuine effort. The subject and the operator are typically the only people able to give evidence on this, particularly if called upon to do so in Court at a later date. Spirometry tests of a driver that occur sometime later after the breath test are of limited value as some lung diseases, e.g. asthma, have within subject variability for some PFT tests.⁴ A subject with a lung disease may be able to successfully provide a breath specimen one day but find due to their condition it not possible another day.¹⁵ This limits the value of post breath test PFT results and reinforces the importance of the role of the operator and their observations of the subject’s cooperation and effort at the time of testing.

5. Conclusion

All patients with asthma and COPD and the vast majority with interstitial lung disease successfully provided a breath specimen using the roadside screening device. Age, gender, BMI and PFT results of the participants were not a factor in determining the success of a breath test. The presence of a lung disease did not indicate if a driver would be unable to provide a breath specimen at the roadside. The failure of the unsuccessful participant may have been due to incorrect technique and lack of understanding of what was required and not lung capacity.

Further studies are needed to characterise the small minority of patients who may have difficulty providing a breath specimen. Also, all the participants were in good health and the lung disease groups were given a bronchodilator; it may be beneficial to perform the study without administering it to investigate their abilities if not taking their medication correctly. With the introduction of the Dräger 7510 additional studies should be carried out using that device.

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Declaration of competing interest

None.

CRedit authorship contribution statement

Sarah Dowling: Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Validation,

Visualization, Writing - original draft, Writing - review & editing. **David Reynolds:** Conceptualization, Data curation, Formal analysis, Writing - review & editing, Investigation, Methodology, Project administration, Supervision, Visualization. **Aoife O'Reilly:** Data curation, Formal analysis. **Geraldine Nolan:** Data curation, Resources, Project administration, Supervision. **Charles Gallagher:** Resources. **Denis Cusack:** Resources.

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References

1. Republic of Ireland road traffic Act 2010. <http://www.irishstatutebook.ie/eli/2010/act/25/enacted/en/pdf>.
2. Honeybourne D, Moore AJ, Butterfield AK, Azzan L. A study to investigate the ability of subjects with chronic lung diseases to provide evidential breath samples using the Lion Intoxilyzer® 6000 UK breath alcohol testing device. *Respir Med.* 2000; 94:684–688. <https://doi.org/10.1053/rmed.2000.0797>.
3. Honeybourne D, Moore AJ, Butterfield K, Azzan L. A study to investigate the ability of subjects with chronic lung diseases to activate the roadside Lion Alcolimeter® SL-400. *Med Sci Law.* 1999;39:337–341. <https://doi.org/10.1177/2F002580249903900411>.
4. Crockett AJ, Rozee M, Laslett R, Alpers JH. Minimum lung function for breath alcohol testing using the Lion Alcolimeter SD-400. *Sci Justice.* 1999;39(3):173–177. [https://doi.org/10.1016/S1355-0306\(99\)72043-5](https://doi.org/10.1016/S1355-0306(99)72043-5).
5. Pellegrino R, Viegi G, Brusasco V, et al. Interpretive strategies for lung function tests. *Eur Respir J.* 2005;26:948–968. <https://doi.org/10.1183/09031936.05.00035205>.
6. *Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD)*; 2017. <https://goldcopd.org>. Accessed October 7, 2019.
7. Global Initiative for Asthma. *Global Strategy for Asthma Management and Prevention*; 2017. <https://ginasthma.org/wp-content/uploads/2019/04/wmsGINA-2017-main-report-final V2.pdf>. Accessed October 7, 2019.
8. Miller MR, Hankinson J, Brusasco V, et al. Standardisation of spirometry. *Eur Respir J.* 2005;26:319–338. <https://doi.org/10.1183/09031936.05.00034805>.
9. Quanjer PH, Tammeling GJ, Cotes JE, Pedersen OF, Peslin R, Yernault J-C. Lung volumes and forced ventilator flows. *Eur Respir J.* 1993;6(16):5–40. <https://doi.org/10.1183/09041950.005s1693>.
10. Odell MS, McDonald CF, Farrar J, Natsis JS, Pretto JF. Breath testing in patients with respiratory disability. *J Clin Forensic Med.* 1998;5:45–48. [https://doi.org/10.1016/S1353-1131\(98\)90009-8](https://doi.org/10.1016/S1353-1131(98)90009-8).
11. Crockett AJ, Schembri DA, Smith DJ, Laslett R, Alpers JH. Minimum respiratory function for breath alcohol testing in South Australia. *J Forensic Sci Soc.* 1992;32(4): 349–356. [https://doi.org/10.1016/S0015-7368\(92\)73091-6](https://doi.org/10.1016/S0015-7368(92)73091-6).
12. Dräger Alcotest® 6510 - Dual Limit Breath Alcohol Screening Device Approved by the Medical Bureau of Road Safety (MBRS) Instructions for Use (2011). <http://www.ucd.ie/mbrs/t4media/Draeger%20Alcotest%206510.pdf> ; Accessed 7th October 2019.
13. MacIntyre N, Crapo RO, Viegi G, et al. Standardisation of the single-breath determination of carbon monoxide uptake in the lung. *Eur Respir J.* 2005;26: 720–735. <https://doi.org/10.1183/09031936.05.00034905>.
14. Enright PL, Beck KC, Sherrill DL. Repeatability of spirometry in 18,000 adult patients. *Am J Respir Crit Care Med.* 2004;169:235–238. <https://doi.org/10.1164/rccm.200204-3470C>.
15. Gomm PJ, Osselton MD, Broster CG, Johnson NMcl, Upton K. Study into the ability of patients with impaired lung function to use breath alcohol testing devices. *Med Sci Law.* 1991;3:221–225. <https://doi.org/10.1177/2F002580249103100305>.