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Research Paper

A clinical investigation into the ability of subjects with lung disease to provide breath specimens using the EvidenzerIRL evidential breath analyser in alcohol intoxicant driving in criminal justice evidence

Sarah Dowling [a,*], David Reynolds [a,1], Aoife O'Reilly [b], Geraldine Nolan [b], Athiná Kranidi [c], Charles G. Gallagher [b], Denis Cusack [a]

[a] Medical Bureau of Road Safety, Health Sciences Centre, University College Dublin, Belfield, Dublin 4, Ireland
[b] St Vincent's University Hospital, Elm Park, Dublin 4, Ireland
[c] CSTAR, Centre for Support and Training in Analysis and Research, School of Public Health, Physiotherapy and Population Science, Woodview House, University College Dublin, Belfield, Dublin 4, Ireland

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ABSTRACT

The EvidenzerIRL instrument has been in use as an evidential breath analyser in the application of drink driving laws in the Republic of Ireland since 2011. The result of the analysis is used as evidence in prosecutions before the Courts in *per se* offences of driving under the influence of alcohol as distinct from screening results at the roadside. This study aims to assist doctors, lawyers and judges in assessing drivers' failure to provide valid evidential breath specimens. Since the introduction of the EvidenzerIRL, approximately 10% of evidential breath tests annually result in failure or refusal to provide a successful breath specimen, this is an offence under Irish road traffic laws. The presence of lung disease has been given as a reason for the driver failing to provide evidential breath specimens. The aim of this study is to assess the ability of subjects with lung disease to provide breath specimens using the EvidenzerIRL. Pulmonary function tests (PFT) were carried out on volunteers from outpatients of the pulmonary laboratory in St Vincent's University Hospital, Dublin (n = 58) and a control group with no underlying lung disease (n = 19). After the PFTs all volunteers were asked to provide breath specimens using the EvidenzerIRL. Fourteen (24%) out of 58 lung disease volunteers failed to provide a breath specimen, no one from the control group was unsuccessful. Thirteen females and one male volunteer could not successfully provide. Female volunteers were more likely to fail to provide than male volunteers. A significant difference was found between the median age of successful (62.2 years) and unsuccessful (69.2 years) lung disease volunteers. Only one PFT, percentage predicted of Forced Expiratory Volume in 1 second (FEV_1), had a significant difference between the mean of successful (86.6%) and unsuccessful (66.5%) lung disease volunteers. A subject with lung disease was more likely to be successful than unsuccessful. Drivers' effort and operators' guidance through the process were found to be crucial parts to a successful outcome.

1. Introduction

Breath testing for alcohol analysis is used worldwide to enforce road traffic laws in relation to drink driving. The result of the evidential breath test analysis in the Police station is used as evidence in prosecutions before the Courts in *per se* offences of driving under the influence of alcohol. Thus, evidential breath testing results are quite distinct from screening results at the roadside from a driver suspected of driving under the influence of an intoxicant and are thus challenged by defence lawyers on both medical and legal grounds. This study aims to assist doctors, lawyers and judges in assessing drivers' failure to provide valid evidential breath specimens. Failure to provide a successful breath specimen for this process can be an offence in many jurisdictions. Drivers arrested under suspicion of drink driving that have failed to provide breath specimens could and have claimed that lung disease has impaired their ability to be successful. Forensic scientists and medical

* Corresponding author.
E-mail addresses: sarah.dowling@ucd.ie (S. Dowling), david.reynolds@ucd.ie (D. Reynolds), aoife.oreilly1@gmail.com (A. O'Reilly), g.nolan@svhg.ie (G. Nolan), athkranidi@gmail.com (A. Kranidi), c.gallagher@svuh.ie (C.G. Gallagher), forensic.medicine@ucd.ie (D. Cusack).
[1] retired.

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doctors have been called to testify in criminal court cases to evaluate if this is true.

Breath testing equipment has evolved over the years since its introduction, with many countries/jurisdictions changing devices and instruments as the equipment evolves. There have been studies worldwide assessing if subjects with lung disease can successfully provide breath specimens with different breath testing equipment. No such studies have been carried out with the EvidenzerIRL. It is an evidential breath analyser and has been in use in the Republic of Ireland since 2011. In the Republic of Ireland, it is a criminal offence under the Road Traffic Acts to fail or refuse to provide breath specimens for alcohol analysis, the law does not distinguish between failure or refusal. A previous published study was carried out in Ireland to investigate if subjects with lung disease could provide a breath specimen using the roadside screening device Dräger Alcotest® 6510.[1] This paper is a continuation of that study using the same volunteers but focussing on the evidential breath analyser. Screening and evidential breath testing are linked in the forensic and legal field, but each has a unique place in forensic analysis. Screening or preliminary breath testing devices are generally used to indicate the presence of alcohol in a breath specimen (a Pass/Fail result in relation to the *per se* limits) whereas evidential breath analysers measure the concentration of alcohol in the breath.

The EvidenzerIRL is used solely in Police stations in Ireland. It uses infrared technology to determine the concentration of alcohol in end expired breath. A driver is required by law to provide two successful evidential breath specimens, only one is required for roadside screening breath tests.[2] The EvidenzerIRL allows a 3-min period for the provision of each breath. Within this period multiple attempts can be made. If a driver has not provided a successful breath specimen and the timer has counted down to zero, the test aborts and the driver may be charged with failure or refusal to provide.[2]

The purpose of this study is to assess subjects with lung disease and a control group to establish if they could successfully provide breath specimens using the EvidenzerIRL. The subjects underwent Pulmonary Function Tests (PFT) beforehand. The PFT results were used to investigate whether there was a lung function parameter(s) most suitable for predicting whether a subject was capable of providing successful evidential breath specimens using the EvidenzerIRL. The results of this study could be used to assist the Court in dealing with "failure to provide" (FTP) cases in the future.

2. Method

This study was carried out by the Medical Bureau of Road Safety (MBRS), University College Dublin (UCD), which is responsible for the approval, supply and testing of all apparatus used to determine the presence and concentration of alcohol in the breath of drivers in the Republic of Ireland,[2] in conjunction with St Vincent's University Hospital (SVUH), Dublin. Ethical approval was obtained from both bodies. Volunteers with lung disease and with no underlying lung disease undertook PFTs and then were breathalysed using the apparatus the Irish police force use. Each volunteer had the details of the study explained to them and was asked to sign a letter of consent before taking part. For this study no alcohol was consumed by volunteers, as a previous study by Honeybourne et al.[3] found the consumption of alcohol did not affect whether someone could successfully provide a breath specimen.

2.1. Subjects

Volunteers with asthma, chronic obstructive pulmonary disease (COPD) or interstitial lung disease (ILD) were selected from outpatients of the pulmonary laboratory at SVUH. A medical doctor categorised lung disease volunteers according to "Interpretative strategies for lung function tests"[4] and classified their severity as either mild, moderate or severe. Severity was graded for COPD patients using guidelines by Global initiative for chronic Obstructive Lung Disease (GOLD),[5] for asthma patients using Global Initiative for Asthma (GINA)[6] steps and for ILD patients using Diffusing Capacity of the lungs for Carbon monoxide results (DLCO) or Forced Vital Capacity (FVC) results, as set out by Dowling et al.[1] Each lung disease volunteer had to meet certain criteria in order to participate; diagnosis with a single pathology, no infection, no change in medication and no alcohol in their system.

A control group made up of volunteers with no underlying lung disease were sex and age matched as far as possible to the lung disease volunteers. They also had to be alcohol free and have no respiratory infection on the day of testing. They were recruited from an advertisement in UCD.

For the lung disease volunteers all testing was carried out in the pulmonary laboratory at SVUH. For the control group all testing was carried out in the MBRS. The same volunteers were used for this study as a previous one using the roadside screening device Dräger Alcotest® 6510.[1]

2.2. Pulmonary Function Tests

The PFTs undertaken by all volunteers were FVC and Forced Expiratory Volume in 1 second (FEV_1). The lung disease volunteers were asked not to take any inhalers on the day of testing. FVC and FEV_1 were carried out before and after the administering of a bronchodilator (Salbutamol). The control group volunteers were not administered a bronchodilator. Forced Expiratory Ratio (FEV_1/FVC) was calculated for each volunteer from the pre- and post- reversibility results if available. Additionally, DLCO was only carried out on the lung disease volunteers. The staff of the pulmonary laboratory followed "Standardisation of spirometry" by Miller et al.[7] guidelines when conducting the PFTs with volunteers. The PFT equipment used in the hospital was from Carefusion, it included the MasterScreen PFT and Body Plethysmography systems with software Sentry suite V2.17. A desktop spirometer, Vivasis Microlab with V2.36 software, was used for the control group in the MBRS. All PFT equipment was operated by SVUH staff.

2.3. Breath tests

Following the PFTs, volunteers were asked to provide one successful breath specimen using a Dräger Alcotest® 6510 screening device while seated. If the breath test was positive for the presence of alcohol they were eliminated from the study. In order to simulate as closely as possible a real-life scenario, the volunteers were requested to wait for a 20-min period following the screening breath test and before the evidential breath tests. In a real-life scenario, the purpose of this 20-min period is to ensure that any residual alcohol in the mouth has dispersed and is in accordance with best international practice.[8] All breathalysing equipment was operated by a scientist from the MBRS.

The evidential breath tests using the EvidenzerIRL were carried out while the volunteer was standing as is the normal procedure in Police stations. The minimum requirement of a breath specimen is a volume of 1.2 L of breath, provided at a flow rate of at least 14 L/min for approximately 5 s. The back pressure has been measured as 0.7 kPa at a flow rate of 14 L/min. These requirements are within the specification as set out in the International Organisation for Legal Metrology (OIML) Recommendation for Evidential breath analyzers R 126 (2012) (E).[8] The volunteers had 3 minutes to provide the first successful breath specimen. In practice up to five attempts could be made within this time frame. If breath specimen 1 had not been provided successfully within 3 minutes the instrument terminated the test and an incomplete statement was printed to indicate an insufficient breath specimen had been provided. If breath specimen 1 was successfully provided the instrument proceeded to breath specimen 2 after a 2-min wait period. For breath specimen 2 there was also a 3-min period to provide the breath specimen. If a successful breath specimen had not been provided within this time for breath specimen 2 the instrument terminated the test and an incomplete statement was printed to indicate an insufficient breath specimen 2.

The volunteers were given specific instructions when performing the breath tests. They were: "1) take a deep breath, 2) make a seal with your lips around the mouthpiece and 3) blow at a steady rate until I tell you to stop." These are the same instructions the Irish police force use. Irish Police Officers also are required to give a legal instruction taken from the Irish Road Traffic Act section 12(1)a.[2] There is scope for the Police Officers to provide further explanation or demonstration if needed. Each officer must undergo a one and half day training course to become certified operators of the EvidenzerIRL instrument. This course is delivered by scientists from the MBRS.

2.4. Data handling

All data were anonymised, and a unique identification number was given to each volunteer. For all outpatients of SVUH no medical files were removed from the hospital. The spirometry equipment calculated the PFT results for FVC, FEV_1 and DLCO as percentage predicted of a normal population as shown in Quanjer et al.[9] From the evidential breath tests the number of subjects who failed to provide and the number of attempts made by each volunteer were recorded. Any relevant comments made by each volunteer were recorded by the operator during the testing.

Data were examined for any volunteer that did not meet the study criteria post testing e.g. respiratory infection on the day of testing. These were then excluded from data analysis. For statistical analysis SPSS® version 24 was used. Normality tests were carried out on each variable. For not normally distributed data (Shapiro-Wilk, $p < 0.05$) non-parametric tests (Mann-Whitney U, Wilcoxon signed-rank test, Fisher's Exact test, Pearson chi square test) were used to compare differences. For normally distributed data (Shapiro-Wilk, $p > 0.05$) parametric tests were used (independent t-tests). A p-value of less than 0.05 was considered statistically significant.

3. Results

Eighty four volunteers (n = 64 lung disease volunteers, n = 20 controls) took part in the study. Participants were limited in number due to availability of patients as volunteers and SVUH resources. Not all volunteers met the study criteria. No one was found to have alcohol in their system. Seven of the volunteers' results were eliminated from further data analysis. The first two volunteers tested (one from the COPD group, one from the ILD group) in the study were excluded due to a different testing procedure for the evidential breath tests. For health and safety reasons, these two volunteers were asked to remain seated to provide the evidential breath specimens. This hindered their ability to provide the breath specimens. Volunteers after this were instructed to stand and a chair was placed behind them with the operator of the EvidenzerIRL mindful of their well-being. From the control group one volunteer was omitted, due to a childhood history of asthma and borderline normal PFT results. Two volunteers had a respiratory infection on the day of testing, so they were omitted. Another did not have a single pathology. One volunteer was eliminated due to ethnicity, they were non-Caucasian, the percentage predicted results calculated by the spirometry equipment was pre-programmed for Caucasians, so their results would not be accurate. Table 1 shows the details of the 77 eligible volunteers (n = 58 lung disease volunteers and n = 19 controls) from each volunteer group by age, sex, disease severity and outcome of the breath test. For individual lung disease groups, the numbers in each were too low to analyse for significant differences for each variable. Data analysis was carried out comparing the unsuccessful and successful volunteers with lung disease. Comparison with the control group was performed where required.

A volunteer was deemed to be successful if within three minutes the EvidenzerIRL had flagged their breath specimen as a "Sufficient specimen" on the screen regardless of the number of attempts made for breath 1 and breath 2. No volunteer in the control group failed to provide a successful breath specimen. Fourteen (24.1%) out of 58 lung disease volunteers were unsuccessful in providing breath specimen 1. A significantly higher proportion of volunteers successfully provided in the control group compared to the lung disease group, with 100% success for controls and 75.9% success for the lung disease groups (Fisher's Exact test, $p < 0.05$), see Table 2. For the lung disease volunteers, the odds of being successful was 3.1. Three from the asthma group, six from the COPD group and five from the ILD group were unsuccessful, see Table 1. Volunteers with mild (one with COPD and three with ILD), moderate (one with asthma, one with COPD and two with ILD) and severe (two with asthma and four with COPD) grading of each lung disease were unsuccessful.

Thirteen female volunteers failed to provide a breath specimen. Only

Table 2
Overall outcome of the breath test.

Volunteer Group	EvidenzerIRL Breath Test Outcome				p value
	Unsuccessful		Successful		
	n = 14		n = 63		
	n	%	n	%	
Control (n = 19)	0	0	19	100	**0.016**[a]
Lung disease (n = 58)	14	24.1	44	75.9	

Bold results = significant results.
[a] = Fisher's Exact test.

Table 1
Details of eligible volunteers.

Characteristic	Volunteer Group							
	Asthma		COPD		ILD		Control	
	n	mean (sd)	n	mean (sd)	n	mean (sd)	n	mean (sd)
Age	19	55.1 (18.15)	19	67.3 (10.95)	20	62.8 (11.36)	19	58.9 (14.29)
	n	%	n	%	n	%	n	%
Sex								
Male	7	37	10	53	12	60	10	53
Female	12	63	9	47	8	40	9	47
Severity Level								
Mild	4	21	5	26	10	50	n/a	n/a
Moderate	2	11	7	37	7	35	n/a	n/a
Severe	13	68	7	37	3	15	n/a	n/a
Breath test outcome								
Successful	16	84	13	68	15	75	19	100
Unsuccessful	3	16	6	32	5	25	0	0

sd = standard deviation.

one male volunteer failed to provide a breath specimen, he was diagnosed with severe COPD. A significant difference was found between the proportion of male and female volunteers with lung disease in their ability to provide a successful breath specimen (Pearson chi square test, $p < 0.001$). For female volunteers, the odds of being successful was 1.23. The odds of men being successful rather than unsuccessful were 22.75 times higher (95% CI = 2.7–190.4, $p < 0.05$) than the odds of a woman being successful, see Table 3.

The age on the day of testing of each volunteer was recorded. A significant difference was found in the median age between unsuccessful and successful lung disease volunteers (Mann-Whitney *U* test, $p < 0.05$). Fig. 1 shows a boxplot of the age split by the outcome of the breath test. Unsuccessful volunteers had a higher median age of 69 years compared to 62 years for successful volunteers. Increasing age by one unit the odds of being unsuccessful are 1.09 (95% CI = 1.01–1.17, $p < 0.05$) times higher than being successful. Body Mass Index (BMI) was recorded for all volunteers, however there was no significant difference found between the mean of successful and unsuccessful lung disease volunteers (Independent *t*-test, $p = 0.892$).

The number of attempts made by volunteers for each breath specimen is shown in Table 4. Any volunteers who failed to provide a successful breath specimen took either three or four attempts within the 3-min period. For breath specimen 1 there was no significant difference found in the number of attempts made between the control group and the lung disease group for successful volunteers (Mann-Whitney *U* test, $p = 0.503$). The mode for number of attempts for successful volunteers was one, 79% of control volunteers and 73% of lung disease volunteers needed only one attempt to be successful for breath specimen 1. There was a statistically significant difference found in the number of attempts taken between successful and unsuccessful lung disease volunteers for breath specimen 1 (Mann-Whitney *U* test, $p < 0.05$). Any successful volunteer on breath specimen 1 was also successful on breath specimen 2.

For breath specimen 2 there was no significant difference found in the number of attempts made between the control group and the lung disease group for successful volunteers (Mann-Whitney *U* test, $p = 0.494$). The mode for number of attempts for breath specimen 2 was also one, 90% of control volunteers and 82% of lung disease volunteers needed only one attempt to be successful. There was no significant difference found between the number of attempts made for each breath specimen by each successful volunteer (Wilcoxon signed-rank test, Control group; $p = 0.705$, Lung disease group; $p = 0.118$).

There was only one set of pulmonary function test results for the control group as they did not perform the reversibility test with the bronchodilator. The lung disease volunteers had been requested not to take an inhaler on the day of testing as reversibility tests would be carried out, however ten of them had taken them already. Therefore, only post reversibility PFT results were available for these volunteers. No significant differences were found between successful and unsuccessful lung disease volunteers for any of the PFTs pre-reversibility with a bronchodilator, see Table 3. Further data analysis was carried out on results from the post reversibility PFTs only. The lung disease volunteers were reduced to 56 as two volunteers did not have reversibility carried out because their initial results were deemed too inconsistent by the physiologist. In the pulmonary laboratory of SVUH if a patient cannot perform consistent baseline spirometry, reversibility can be unreliable as their technique may improve in the second set of spirometry tests to give them a false positive response, therefore their results were omitted from data analysis. These two volunteers were successful in providing breath specimens.

For the post reversibility PFTs both FEV_1/FVC (Mann-Whitney *U* test, $p = 0.179$) and FVC % predicted (Independent *t*-test, $p = 0.251$) were found to have no significant differences between successful and unsuccessful lung disease volunteers.

A significant difference was found between successful and unsuccessful lung disease volunteers for FEV_1% predicted (post) results (Independent *t*-test, $p < 0.05$). For unsuccessful volunteers, the mean result was lower at 66.5% compared to the successful lung disease volunteers with a mean of 86.6%, see Table 3. An increased FEV_1% predicted (post) result was associated with an increased chance of being successful by a factor of 1.04 (95% CI = 1.009–1.072, $p < 0.05$). Fig. 2 shows a boxplot graph of the spread of results for FEV_1% predicted (post) for unsuccessful and successful lung disease volunteers using the EvidenzerIRL, however there is considerable overlap between the two groups. The minimum result for successful lung disease volunteers was 41% and for unsuccessful volunteers was 34%. The maximum results for successful and unsuccessful lung disease volunteers were 129% and 116% respectively.

For DLCO and DLCOc (DLCO value corrected for the patient's haemoglobin) PFTs no significant difference was found between successful

Table 3
Age, BMI, PFT results and sex of lung disease volunteers split by outcome of the breath test.

Variable	EvidenzerIRL Breath Test Outcome				p value	Unadjusted Odds Ratio (OR)		
	Unsuccessful		Successful			OR	95% CI	p value
	n	median (range)	n	median (range)				
Age (years) (n=58)	**14**	**69.2 (60.70–82.07)**	**44**	**62.2 (22.76–83.43)**	**0.009**[a]	**0.920**	**0.858–0.986**	**0.019**
Pre FEV_1/FVC (n = 48)	9	73.8 (29.77–90.41)	39	72.3 (34.84–104.20)	0.640[a]	0.995	0.951–1.041	0.835
Post FEV_1/FVC (n = 56)	14	65.8 (29.48–94.52)	42	72.4 (32.93–105.70)	0.179[a]	1.029	0.995–1.065	0.098
	n	mean (sd)	n	mean (sd)				
BMI (kgs/m^2) (n = 56)	14	26.7 (4.12)	42	27.0 (5.57)	0.892[b]	1.008	0.896–1.135	0.889
Pre FEV_1 (% predicted) (n = 48)	9	77.7 (23.67)	39	81.4 (23.21)	0.663[b]	1.007	0.976–1.040	0.655
Pre FVC (% predicted) (n = 48)	9	94.0 (25.85)	39	96.7 (21.91)	0.749[b]	1.006	0.973–1.039	0.742
DLCO (% predicted) (n = 49)	9	60.2 (18.61)	40	68.8 (19.43)	0.233[b]	1.023	0.985–1.062	0.233
DLCOc (% predicted) (n = 49)	9	60.0 (19.11)	40	69.6 (18.64)	0.172[b]	1.027	0.988–1.067	0.176
Post FEV_1 (% predicted) (n=56)	**14**	**66.5 (26.83)**	**42**	**86.6 (20.62)**	**0.005**[b]	**1.040**	**1.009–1.072**	**0.010**
Post FVC (% predicted) (n = 56)	14	92.2 (21.86)	42	100.0 (21.49)	0.251[b]	1.018	0.988–1.048	0.248
	n	%	n	%				
Sex (n=58)								
Male (n=29)	**1**	**3.4**	**28**	**96.6**	**<0.001**[c]	**22.75**	**2.718–190.421**	**0.004**
Female (n=29)	**13**	**44.8**	**16**	**55.2**				

Bold results = significant results. sd = standard deviation.
[a] = Mann-Whitney U test.
[b] = Independent *t*-test.
[c] = Pearson chi square test.

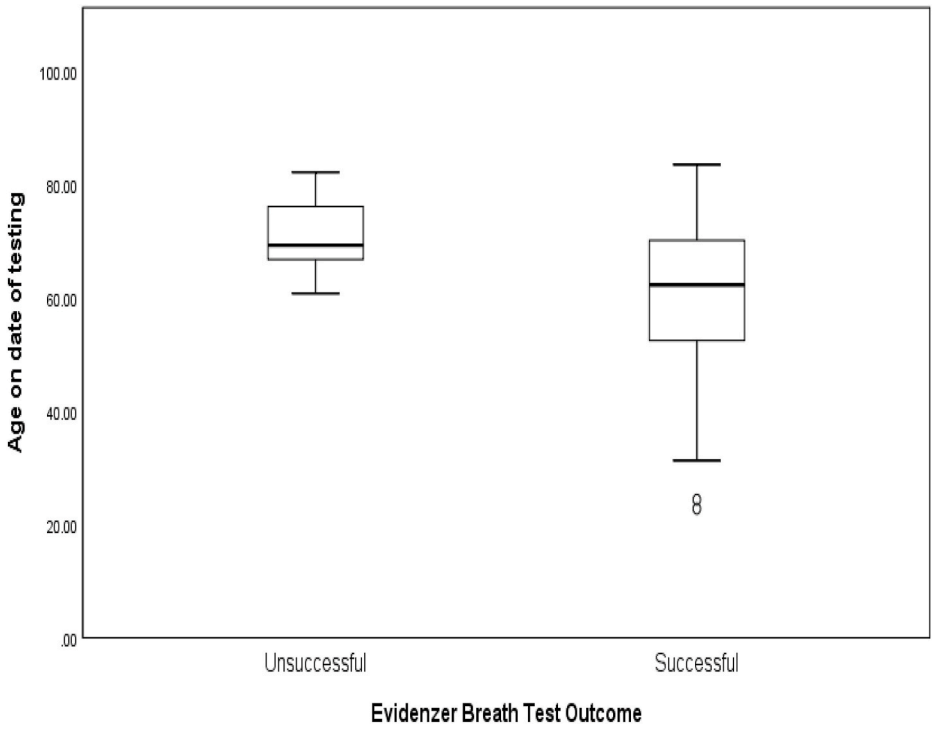

Fig. 1. A boxplot of age (years) on the day of testing for the lung disease volunteers split by outcome of the breath test. The bottom and top of each box indicate the 25th and 75th percentiles, while the top whiskers indicate the maximum results. The two circles indicate two outliers.

Table 4
Number of attempts by volunteers.

No. of attempts	Volunteer Group					
	Lung Disease (n = 58)				Control (n = 19)	
	Unsuccessful		Successful		All Successful	
Breath 1	n = 14	%	n = 44	%	n = 19	%
1 attempt	0	0	32	73	15	79
2 attempts	0	0	8	18	4	21
3 attempts	7	50	3	7	0	0
4 attempts	7	50	1	2	0	0
Breath 2	n = 0	%	n = 44	%	n = 19	%
1 attempt	n/a	n/a	36	82	17	90
2 attempts	n/a	n/a	7	16	1	5
3 attempts	n/a	n/a	1	2	1	5

and unsuccessful lung disease volunteers, see Table 3. Only 49 out of 58 volunteers with a lung disease completed these PFTs, this was due to incorrect technique or insufficient lung capacity.

4. Discussion

Defence lawyers have challenged *per se* alcohol results and failure to provide prosecutions on both medical and legal grounds. The importance of medical evidence in FTP cases before the criminal courts is a core function of forensic medicine and science in criminal jurisprudence. This study was designed to address this question to assist doctors, lawyers and judges in evaluating FTP arising from both defence and prosecution submissions and arguments. While there have been previous studies worldwide investigating if lung disease affects the ability to provide breath specimens for alcohol analysis this is the first one with the Evidenzer. It is in use in Sweden, Norway, Finland as well as the Republic of Ireland. In 2019, the number of evidential breath tests carried out in the Republic of Ireland was 5,372.[10] The overall percentage of these tests flagged as FTP was 10%,[10] however when the 60 plus age group was examined in the MBRS 2019 annual statistics (unpublished) the FTP rate more than doubles to 21%. The gender profile for all evidential breath tests in 2019 (including the 60 plus age group) was 86% male and 14% female.[10] For FTP cases it was 73% males and 27% females for all age groups but changes to 66% males and 34% females for the 60 plus age group (unpublished). All female drivers breathalysed in 2019 had a higher percentage of evidential breath tests flagged as FTP at 19% compared to all male drivers breathalysed which was 8.5% (unpublished). The subgroup of over 60 year olds shows an increase on these percentages to 51% for female drivers and 16% for male drivers. The higher percentage of females that fail to provide compared to male drivers shows that female drivers, especially for the older age group, find it harder than males to provide a breath specimen which is also seen in the results of this study. Sex and age were contributing factors in the ability of the volunteers to successfully provide breath specimens using the EvidenzerIRL, with an increasing age associated with an increased chance of being unsuccessful. Female volunteers were more likely to fail to provide a breath specimen than male volunteers, only one male failed to provide. This male volunteer was 73 years old and suffered from severe COPD, he had the lowest FEV_1% predicted (34%) value of all male volunteers recorded during this study. He took four attempts and the operator of the evidential breath testing instrument commented that he "almost provided" on all four attempts. Unsuccessful female volunteers were distributed over the three lung disease groups with COPD and ILD having five in each group. The youngest unsuccessful female volunteer was 60 years old and was diagnosed with severe COPD.

Seccombe et al.[11] found that subjects with severe ILD were more likely to fail to provide a breath specimen (two in three) compared to subjects with severe COPD (one in six). In this EvidenzerIRL study approximately equal numbers from the ILD (five) and COPD (six) group failed to provide a specimen. The blowing requirements for each evidential instrument are factors in the success rates for these studies and may contribute to varying degrees depending on the type of lung disease. The Intoxilyzer® 8000 used by Seccombe et al.[11] has a breath provision time of approximately 7.5 s, this time is difficult to sustain for some subjects with severe ILD. For the EvidenzerIRL the minimum time

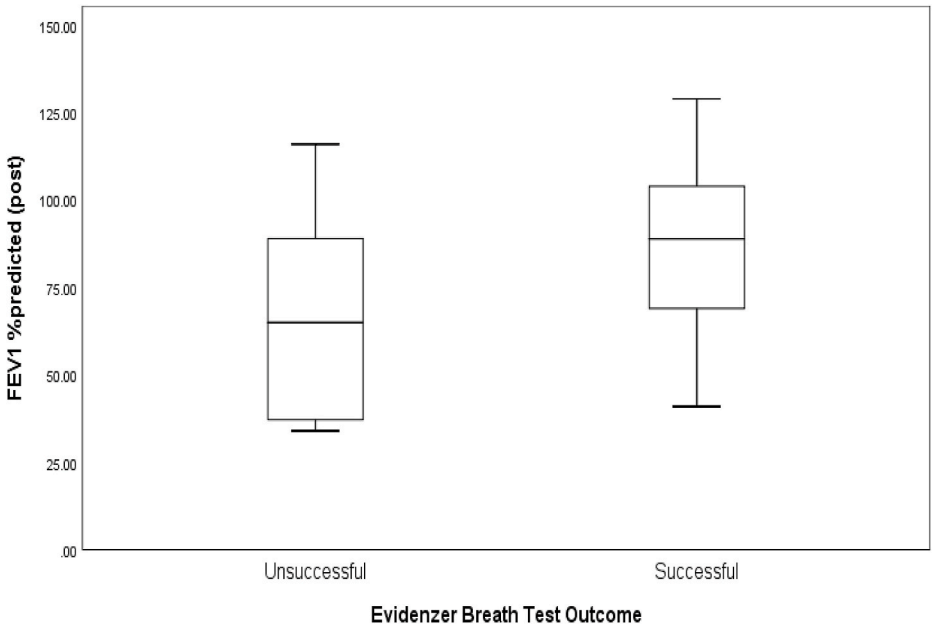

Fig. 2. A boxplot of FEV_1% predicted results for lung disease volunteers split by outcome of the breath test. The bottom and top of each box indicate the 25th and 75th percentiles, while the bottom and top whiskers indicate minimum and maximum results, respectively.

is 5 s, no subjects with severe ILD were unsuccessful in this study but four with severe COPD were unsuccessful, including the only male volunteer to fail to provide. The volunteers with severe COPD could have found the EvidenzerIRL's higher flow rate of 14 L/min difficult to reach and maintain compared to the 8L/min for the Intoxilyzer® 8000 thus in this study a higher number of severe COPD volunteers failed to provide (four out of seven volunteers). However, severity of each lung disease did not appear to indicate the outcome of the breath test, as eight unsuccessful volunteers had mild or moderate severity grading, but this study had low numbers for each severity level therefore no statistical inference could be made. Further studies could be carried out with males who suffer from severe COPD to investigate their success rate. The presence of lung disease did influence the outcome of the breath test, although the lung disease volunteers were still more likely to be successful than unsuccessful and no volunteer from the control group failed to provide.

The post reversibility FEV_1% predicted value was found to be the one PFT that could be used to predict the outcome of a breath test. The mean result for unsuccessful lung disease volunteers was significantly lower than successful lung disease volunteers and the likelihood of success increased with an increasing FEV_1% predicted value. Four of the unsuccessful volunteers suffered from severe COPD. FEV_1 results are used to diagnose the severity of COPD with a FEV_1 percentage predicted value of less than 50% classified as severe.[5] However, there is still overlap of FEV_1% predicted results between unsuccessful and successful volunteers, see Fig. 2. A predictive failure cut off result of less than 1 L for FEV_1 was reported by Honeybourne et al.[3] Again, overlap for FEV_1 results between unsuccessful and successful volunteers was noted in that study. Honeybourne et al.[3] had a 30% failure rate for subjects with lung disease using the Intoxilyzer® 6000UK (flow rate = 12 L/min), while Seccombe et al.[11] had a lower failure rate of 16% using the Intoxilyzer® 8000 (flow rate = 8 L/min). These blowing requirements are slightly different to the EvidenzerIRL, with a minimum flow rate of 14 L/min and a lower back pressure (1.8 kPa for the Intoxilyzers[3] compared to 0.7 kPa for the EvidenzerIRL). This study had a failure rate of 24%, 6% lower than Honeybourne. Therefore, their reported cut off value of 1 L for FEV_1 may not be applicable to the EvidenzerIRL. This highlights the importance of performing these studies on specific evidential breath analysers.

From our previous published paper using the screening device Dräger Alcotest® 6510 the success rate was found to be very high at 98.7%.[1] That study found that the presence of lung disease (asthma, COPD or ILD) did not indicate if a driver would be unable to successfully provide a breath specimen.[1] Only one volunteer failed to provide a successful breath specimen using this device. It was a female volunteer suffering from ILD with moderate severity.[1] The EvidenzerIRL and the Dräger Alcotest® 6510 have similar but different blowing requirements. Both require 1.2 L of breath but the Dräger Alcotest® 6510 requires a flow rate of 13 L/min to trigger the device while the EvidenzerIRL has a minimum flow rate of approximately 14 L/min. The minimum blowing time is one of the main differences, with the screening device at a shorter time of 2 s compared to 5 s for the EvidenzerIRL. The back pressure or resistance the subject experiences while attempting to provide a specimen is also substantially greater with the EvidenzerIRL due to its design. The combination of these two requirements could cause the higher failure rate with the EvidenzerIRL. Screening and evidential breath testing are closely related but each has a unique place in the forensic world of breath testing. Having lower blowing requirements at the roadside ensures the highest number of successful breath tests and prevents unnecessary detention of drivers who may be negative for alcohol but may fail to provide if the blowing requirements were too difficult to achieve. Evidential breath analysers are generally more sophisticated than screening or preliminary breath testing devices as the concentration of alcohol maybe used to convict the driver if they are over the legal limit. In the Republic of Ireland there is a safeguard based on case law if the evidential breath tests are not successful in the Police station, the Police Officer is required to offer the driver an option to provide a blood or urine specimen.[12] Penalties for failing to provide a breath, blood or urine specimen are a fine not exceeding €5000 and/or imprisonment not exceeding six months.[2]

The Irish road traffic law accommodates for a statutory defence for failing to provide evidential breath specimens. Section 22 of the Road Traffic Act 2010 states "it shall be a defence for the defendant to satisfy the court that there was a special and substantial reason for his or her refusal or failure".[2] This allows for a medical defence or reason for failing to provide. This is only allowed as a defence if the driver has complied with the requirement to have a blood specimen taken or provide a urine specimen in place of the two breath specimens. There is

no definition of "a special and substantial reason". The Supreme Court case, DPP v Cagney,[12] described it as a "transient medical condition". In this case the driver had told the Police Officer at the time of the breath test that they had no medical condition to prevent them from providing but did fail to provide. At trial the driver indicated that they had a cough and a chest infection, a general practitioner had examined the driver the evening following their arrest and found no clinical symptoms but diagnosed a post viral condition and stated the driver would be unable to provide a breath specimen.[12] In his book "Drunken Driving", Staunton[13] states there are very few reported cases in Ireland that examine "a special and substantial reason" as a defence and therefore he looks at case law in England and Wales to assist with the interpretation of the law. In England and Wales a "reasonable excuse" needs to be provided as a defence for failing to provide a breath specimen, some examples were not related to lung function but due the defendant's "emotional distress" and that they were "mentally unable" due to suicidal ideation to provide breath specimens, from Spalding v Paine.[13] Other examples including chronic bronchitis and asthma have on occasion been accepted in courts as a "reasonable excuse".[14] Our study recorded a higher number of successful asthmatics than unsuccessful (16 successful out of 19), but all volunteers were in a stable condition and carried out the breath tests after the administration of a bronchodilator. From these cases the reasons given by drivers for failing to provide is not simply due to physiological characteristics or a diagnosed medical condition, but other circumstances need to be considered.

For evidential breath analysers the goal of breath provision is to capture deep lung air. This is defined as a specimen of air taken at the end of the expiration of the breath which gives the best estimate of the alcohol content in the subject's system at the time of testing. The evidential breath provision technique is different from PFTs. For the EvidenzerIRL it is a steadier, more consistent, and slower blowing effort compared to the PFTs, this is to ensure a sample of deep lung air is provided. Both do require the subject to empty their lungs of air. During PFTs subjects are instructed to exhale with maximal force.[7] If this was done using the EvidenzerIRL the subject might find they cannot provide a successful breath specimen at the required flow rate for the minimum time. Therefore, their attempt could be flagged as "Insufficient specimen". While there was no statistically significant difference between the number of attempts to provide a first or second breath specimen by each volunteer, it appears that some volunteers used the experience of providing the first breath as a guide to providing the second breath specimen. This included a 68-year-old female volunteer who suffered from moderate COPD, a smoker with only one lung. This volunteer reported to the EvidenzerIRL operator that she had a lung removed a few years before this study. She took four attempts on the first breath and then only needed one attempt on the second breath specimen. The operator commented she "did not blow hard enough on her first three attempts". The presence of lung disease did not prevent her successfully providing but it emphasised the importance of technique for somebody with reduced lung capacity. Subjects with a larger lung capacity (which males generally have when compared to females) may not be as sensitive to an incorrect technique compared to subjects with lower lung capacity. In a real life scenario for a suspected drunk driver, there is only one set of instructions for the breathalysers i.e., no PFTs are involved so comprehension should be simpler. Any volunteer who was successful on breath specimen 1 was successful on breath specimen 2, the physical exertion of providing a successful first breath specimen did not exhaust any volunteer to the extent that they could not provide breath specimen 2 successfully after at least a 2-min wait. Therefore, it can be reasonably concluded that fatigue was not a factor for successful volunteers. All volunteers were healthy and their condition stable at the time of testing. The lung disease group did not find it harder than the control group to provide a successful breath specimen based on the number of attempts made.

For unsuccessful volunteers there was a significantly higher number of attempts taken to provide for breath 1 compared to successful lung disease volunteers. However, this is as expected because once a successful attempt is made the subject is not requested to make any further attempts and the instrument progresses to the next stage of the breath test sequence. All unsuccessful volunteers had either three or four attempts over the 3-min period to provide a breath specimen; this number of attempts is a realistic number to fit into this time frame. No one was so tired or fatigued after one attempt that they could not try at least two more times. However, for some unsuccessful volunteers, their attempts may have become weaker with each effort due to their lung disease or they may not have been able to grasp the technique. There is a 40 s period between attempts while the instrument goes through a purge cycle that allows the volunteer to catch their breath if required; multiple attempts are not made directly after each other. In annual statistics from the MBRS in 2019 (unpublished) 18% of FTP breath tests had one breath specimen provided successfully with breath specimen 2 not completed. Results from this study would indicate that these drivers should have successfully provided a second breath specimen; however, their failure may have been due respiratory infection, untreated lung disease, inconsistent technique, or reduced effort.

As discussed already, some of the successful volunteers were able to gauge the technique from multiple attempts on breath 1 but this may not have been the case for some of the unsuccessful volunteers. In performing PFTs there is a percentage (approximately 10%) of subjects that cannot perform them consistently.[15,16] The success of repeatable PFT results has been contributed to by the skill and experience of the operator to coach the patient through the manoeuvres and very little by patient characteristics.[15] Unlike PFTs, evidential breath tests do have minimum requirements to meet in terms of flow rate, volume of breath and a 3-min time window to successfully provide a breath specimen. Unsuccessful volunteers may be part of the 10% cohort that cannot consistently perform PFTs. This, coupled with their impaired lung function, may have contributed to their failure to provide despite multiple attempts to do so.

For evidential breath testing there may be other reasons why subjects do not provide successful breath specimens. The EvidenzerIRL does not record how many attempts unsuccessful drivers made or the effort made for each one, only an incomplete statement reporting the test as "Specimen Incomplete" or "Specimen Not Provided" is printed and recorded in the memory of the instrument. The operator of the evidential breath testing instrument and the driver may be the only people present during the breath test in Police stations and therefore the only people to judge the effort made by the driver. The evidence of the operator, a Police Officer, is of particular importance as any PFTs carried out post evidential breath tests by the driver to aid them in their defence may be days to months later. Fluctuations of pulmonary function for an individual over time occur for many reasons[4,14] e.g., a respiratory infection or type of lung disease, this can hinder forensic scientists and medical doctors in assisting the Court. For this study all PFTs took place the same day as the evidential breath tests. The effort exerted by the driver is a key piece of evidence for the Court. In the Supreme Court case DPP v. Moorehouse[17] the driver was unable to comply with the Police Officer's instructions to make a seal with their lips around the mouthpiece, according to the Police Officer their breath did not go down the breath tube. In this instance the physiological characteristics of the driver were of secondary importance. The operators need to know the best technique for breath provision and recognise when this not being understood or not being adhered to. The operator's instructions are one of the main factors in the success of a breath provision for medical and forensic purposes.[11,15,16] It should be regarded as a joint effort between driver and operator to produce a successful breath test. During the training of operators, it is therefore of great importance to emphasise it is a collaborative process. An improvement in training of operators that was suggested in our previous paper was to emphasise that elderly female drivers find it more difficult to provide breath specimens,[1] which we have also reported in this study.

The consumption of alcohol also adds complications for the operator.

While Honeybourne et al.[3] found alcohol, albeit at breath alcohol levels of approximately 35 μg/100ml, is not a factor in the ability of people with impaired lung function to provide a breath specimen successfully, alcohol consumption can affect a person's ability to listen and understand instructions. Clinical signs and symptoms of increasing breath alcohol concentration include increasing loss of comprehension, attention, and judgement.[18] These symptoms add difficulty for the operator in gaining the cooperation of the driver, especially if the driver feels it is disadvantageous to them to successfully provide a breath specimen. In this study all volunteers cooperated fully, and genuine efforts were made by all. Very high levels of blood alcohol (350–500 mg/100 ml) have been reported to cause respiratory depression and even death,[18] but MBRS annual statistics show that 22% of drivers provided breath specimens successfully at alcohol levels of over 66 μg/100 ml in 2019.[10] All unsuccessful volunteers failed either due to lung deficiencies or an inability to master the correct technique.

5. Conclusion

The findings of this study will assist the justice process in criminal prosecutions before the Courts and will also assist doctors (including respiratory physicians) in forming an opinion on the ability of driver subjects, their patients, to provide a valid breath sample when required to do so by investigating Police Officers. All volunteers in this study were free of any respiratory infection at the time of testing, the lung disease group volunteers were stable, had no recent change in medication and they had been given a bronchodilator before attempting the evidential breath tests. Under these conditions lung disease may affect the ability of a driver to successfully provide a breath specimen, however, volunteers with lung disease were still more likely to be successful than unsuccessful. As a guideline to assist the Courts this study found female drivers were more likely to fail to provide evidential breath specimens compared to male drivers, with increasing age adding to the failure rate. Only FEV_1 had significant differences between successful and unsuccessful volunteers but with overlapping results. Due to this, the emphasis should be put on the quality of the operators' instruction to the driver and their enforcement of correct technique to ensure the success of evidential breath provision.

If a driver with lung disease who is free from respiratory infection can make one attempt at providing a breath specimen using the EvidenzerIRL then multiple attempts could be made. In addition, for a driver who successfully provides one breath specimen, the physical exertion involved does not cause sufficient fatigue to prevent a second successful breath specimen. A driver diagnosed with lung disease who is not taking their medication correctly or a driver with a respiratory infection, is outside the scope of this study.

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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, Review, Resources, Project administration, Supervision. **Athiná Kranidi:** Writing – review & editing, Formal analysis. **Charles G. Gallagher:** Review, Resources. **Denis Cusack:** Review, Resources.

Declaration of competing interest

None.

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