



# Inspire

*The Journal of the Association  
for Respiratory Technology &  
Physiology*

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# FIRST WORD

1ST APRIL 2015

VOLUME 16, ISSUE 1



Welcome to the new, 'post-conference' issue of 'Inspire'. The conference was, as usual, superbly organised to allow time for education, fun and even the odd venture into Blackpool centre.

The content from the conference can be found [here](#) (for ARTP members) and this issue has coverage of the accepted [abstracts](#), the minutes from the [AGM](#), news of just who were the winners in the coveted [ARTP Manufacturer awards](#) and possibly the occasional [picture](#) here and there. What with all this conference content there is space enough merely for one [original article](#) in this issue – a review of many (if not all) of the factors requiring consideration in order to standardise inhaled challenge tests. One of the pleasures to be had in being Inspire Editor (and there are, of course, many) is the chance to read such articles in detail while formatting them for publication.

Looking at this article, the abstracts and indeed the [AGM](#) minutes (!) should remind us what the ARTP is for. The AGM showed the breadth of publications, courses and collaborations the ARTP is involved with – highlighting the benefits of being a member of the ARTP and I list some of them here once more in order to convince you to join if you have not yet done so. See [here](#) for the full list and don't forget if under 35 years ARTP members may join the [European Respiratory Society](#) for free.

- Discounted Training Course fees
- Subsidised conference attendance
- Grants available (i.e. ARTP)
- Competitive membership fees
- e-Inspire / eXhale / SNews
- Textbooks
- Email Forum
- Website Resources
- Active Committees
- Tax deductible

The ARTP exists for its members and should be used as a way of improving your knowledge. Don't be afraid to use it and ask questions or get involved. A recent [post](#), from a different sphere of science, summed this up and perhaps this could be something to explore within our organisation but as ever feel free to email us at [inspire@artp.org.uk](mailto:inspire@artp.org.uk) with suggestions for improving the journal.

**AIDAN LAVERTY**  
**PAUL BURNS**



Dr. Karl Sylvester

ARTP Honorary  
Chair

## A WORD FROM THE CHAIR

This truly is a bumper edition of Inspire this month, primarily due to the inclusion of the excellent scientific research that was presented at this year's ARTP conference. The conference this year was outstanding, with excellent speakers, lots of audience participation and superbly organised as always by the team at EBS. There was an amazing atmosphere and I received lots of positive feedback with some suggesting this could have been the best ARTP conference ever!! As much as that pleases me it also means we have a lot of hard work to do to impress you all again next year, which by the way will be our 40th Anniversary year.

Most of our events committee and team

about what they would like to see at the conference, both during the educational sessions and the evening's entertainment. Please do feel free to contact me with any suggestions you may have.

We have an edition of Inspire packed with conference material, information and updates for you. Our first article by Jan Rezulski at Quintiles reminds us that we should never rest on our laurels and continue to question what we do every day. Science is about continually questioning the world around us. About asking why and if that why is, "why do we do it that way?" the answer should never be "because that's the way we've always done it". As members of the brightest and best



have visited the venue which does look very impressive. There are a few extra surprises planned, so if you weren't able to attend last year (or even if you were) make sure you sign up to come to the next one. We're always pleased to hear suggestions from the membership

physiological profession of the scientific community we uphold the quality standards of respiratory and sleep technology and physiology. We should always be ensuring that we deliver our services to current best practice and thriving to find better, more improved



ways of delivering our services for the patients we see.

With this in mind it was another year of excellent research presentations, both those presented as posters and as oral presentations. The quality and calibre of the research being presented seems to grow and grow each year. There were some concerning service delivery and improvements that could be made and others around new techniques for assessing lung function, hopefully adding and complementing our existing techniques. It was great to see some new faces at these sessions presenting their work. I hope all those presenting have submitted their research as abstracts to one of the international meetings, for example ERS or ATS. If not this year, hopefully next year. It's a great opportunity to present your work in front of international experts in the field of respiratory medicine. We are fortunate within the ARTP to have a number of scientists that have already been through this process and have vast amounts of experience in formulating, conducting and presenting results of their research trials. If you are thinking of conducting some research or already have but are wondering how best to present it then the ARTP would be delighted to assist you should you feel you need it. Just drop us a line and we'll make sure your request for information is directed to the right

people.

The conference is always a great opportunity for me to publicly thank all the people that make the ARTP the best professional body around. One person I'd like to make a special mention of is Nigel Clayton. Nigel has been our Manufacturers Liaison Committee Chair for longer than he probably cares to remember. Just when he thought he could hang up his boots circumstance has necessitated his return to the fold but hopefully only for a short sabbatical for his sake. Nigel has been a fantastic MLC chair and I'm sure all the manufacturers will agree with me. Every year he produces the manufacturers' survey which is used to determine who wins the best respiratory and sleep manufacturers awards and presents these at our conference. He also puts together the On The Blower article in each edition of Inspire, which is again brilliant in this edition. So my heartfelt thanks go to Nigel for his many years service for ARTP under a number of different Chairs. He has performed a sterling job and he will be a hard act to follow.

Until next time, feel free to contact me at [chair@artp.org.uk](mailto:chair@artp.org.uk).



Dr Brendan G  
Cooper  
President, ARTP

# ARTP Presidential Address 2015

Although our annual conference was very well attended at Blackpool back in January (was it really over 3 months ago!!!) many of you were unable to attend and will have missed the Presidential address. I am providing this written version so you can share the points, consider the message and add your own thoughts in an [email](#) if you are so inclined.

As I complete my first full year as President, I am proud of leading a professional body that not only cares, but believes in caring for patients - a workforce that stands up for high standards and practices best quality. Why do we do this? It is because as Healthcare Professionals this is essential to our role and it's our legacy. At the Annual Conference we celebrate your skills, professionalism and dedication to patients as the best Healthcare Physiologists not just in the UK...but in Europe and probably the world.

Like all NHS clinical staff we are experiencing unprecedented pressures on activity, workload and severity of disease. However, from talking with many of you, despite the pressures, the high standards of quality and care not only persist, but they get better. Respiratory medicine without respiratory physiology is like night-driving without headlights ...you can do it, but it won't end well! Your hospital's ability to deliver their targets and quality care is due in part to your brilliant efforts.

At conference we saw the excellence not just in our student's achievements, but also in their brilliant trainers and leaders who have taught them "the ARTP way". Our committees have been organised, hardworking and generous of their own time - despite having busy day jobs, busier family life and greater expectations put upon their time. At this time of a general election, after a difficult season of winter pressures, is this really the time to continue a prolonged pay freeze on the best public servants the country has? Please understand, I've no great faith in any of the political parties, who during the election cynically "creep up" to the electorate now only to return to the "Westminster bubble" and follow their partisan prejudices playing political games with OUR Health Service! Whilst we have a system closer to democracy than many countries, we have a long way to go in many respects. Vote wisely and challenge your election candidates about Healthcare Scientists, the NHS and the future of healthcare.

If we were to have a national campaign to advertise our ARTP values, beliefs and standards it might be "Nous sommes ARTP"; that's not trivial or glib, it reflects the spirit of our professional body, the recognised respect from other scientists and our rich legacy of nearly 40 years of excellence in respiratory and sleep healthcare. At conference we celebrate the brilliant jobs that you do, the day-in/ day-out grafting, the extra caring, the staying late, the mutual support for

each other and the insistence on only the best for our patients. Take pride in your scientific skills and standards, they are your gifts and you are very exceptional people. I am very privileged to be your President and regularly tell as many people as I can that ARTP is the best, we are the best....."Nous sommes ARTP!"



Our Presidential Award is for an ARTP member who has shown an exemplary contribution to the profession despite experiencing difficult personal circumstances. Our 2015 Presidential Award winner has worked at every level of healthcare for over 4 decades, establishing services, inspiring others, working in Education, on Executive Committees and has been a great promoter of R&D. This individual has taken responsibility for a difficult agenda, fighting for change, battling resistance. Our winner has reformed, modernised and delivered training programmes; they have been involved in fights, personal attacks, fall-outs, arguments and lot of very tense meetings and has done a lot of soul-searching.

Some say the NHS is a political football, and we know football is a game of two halves: government half-wits and half-hearted civil servants – but this never stopped our award winner's drive and determination to get the job done.

There are many senior ARTP people here who have worked with (and sometimes against) our award winner, but all recognise the drive, passion, leadership qualities, ambition and vision, creating the "ARTP way". In the last few years, she had to balance her home/work life to personally nurse her terminally ill mum.

The 2015 ARTP Presidential Award went to our very own Chief Scientific Officer for England to recognise her personal struggle to establish Modernising Scientific Careers and for being the greatest CSO this country has ever seen - Professor Sue Hill, OBE. I hope the drive, determination and leadership that Sue Hill shows will inspire many of you to push your career and your professional life further so in the future we have many more great leaders to fly the flag for quality, standards and best care. We need strong representation and advocates to shout your praises from the rooftops, so that the public know that they are getting brilliant value for money from the NHS.

Have a great summer and keep up the great work.

Best regards,

Brendan

## Challenging current perspectives on the 2 minute tidal breathing method for bronchial challenge and providing a new rationale for modifying current practice

[Mr. Jan Rezulski](#), Clinical Physiologist, Quintiles Ltd, London SE1 1YR

### BACKGROUND

The current recommendations and guidance on the 2 minute tidal breathing method for performing bronchial challenge testing are based on the original work of Donald Cockcroft, where a Wright nebuliser was used at a flow rate of 7L/min of compressed air which yielded a nebulisation rate of 0.13 ml/min.<sup>1, 21</sup> Unfortunately the significance of this precise output or the 2-minute inhalation duration is largely unknown, however it has become the standard for the performance of such tests.

It would appear to make little sense to standardise the output of a tidal breathing nebuliser system since the patient's breathing profile and usage time determine the amount of drug received. Furthermore, current bronchoprovocation models such as Methacholine or Allergen refer to a Provocative Concentration as opposed to a provocative dose that is required to result in a 20% fall in FEV<sub>1</sub>. Dose or actual drug output as opposed to total aerosol output cannot be accurately determined using a tidal breathing method without advanced analysis of residual volume in the nebuliser, and thus the one variable that may be somewhat controlled in terms of nebuliser efficiency is the flow rate at which it is operated, aiming to standardise the particle size generated.

It has been long established that droplet size within the aerosol is a critical factor in achieving efficient delivery of the drug to the correct part of the respiratory tract<sup>17</sup>. In this

document we will aim to rationalise current practice and potential for change based on own observations combined with a meta-analysis of work already in existence. We will also aim to address the potential efficacy and safety considerations based on modifying current practice in the tidal breathing bronchoprovocation models.

### DISCUSSION

There is good evidence that altering the flow or driving pressure into a jet nebuliser greatly influences the particle size generated in the vapour. Current recommendations to standardise the nebuliser output inadvertently results in using nebulisers across a range of flows/pressures. This in turn moves further away from the standardisation of the particle size generated by such nebulisers.

It is of concern that, by not using the recommended flow rate in order to obtain the recommended nebuliser output, one may not be using the nebuliser correctly and alters the particle size of the aerosol outside of the optimum respirable range.

By standardising the output of the nebuliser to 0.13ml/min, one inadvertently generates a requirement to use a nebuliser across a range of flow rates/driving pressures resulting in ever changing aerosol properties such as: particle size, total drug delivery as well as the deposition characteristics in the lung. This "standardisation" in fact creates greater variability.

Since the 2-minute tidal breathing method itself introduces significant variables such as the

breathing pattern, and that this type of nebuliser is not often used to deliver a specific dose but to expose the lungs to a specific concentration, we can postulate that the method and effectiveness of delivery is of key importance and a focus on the correct particle size delivery should be the aim of standardisation of the use of jet nebulisers. In order to highlight some issues with regards to nebulised drug delivery to the airway we must consider a number of topics:

### **The DeVilbiss 646 nebuliser**

Jet nebulisers have become a primary method of delivery of inhaled drugs to patients with asthma. Nebulisers are also frequently used to administer agents for bronchial challenges such as Methacholine or allergen. For methacholine provocation tests, the DeVilbiss 646 is the nebulizer of recommendation<sup>22</sup>. This nebuliser can yield variable particle sizes depending mainly on its output flow rate<sup>9</sup> and at a flow rate of 6 L/min particles were aerosolised to a

mean of 6.0 micron, and at 12L/min, methacholine is aerosolized to particles of 3.7 microns<sup>23</sup>. The DeVilbiss 646 nebuliser has been widely used and is currently the device of choice here at Quintiles Drug Research Unit in London. It is used by attaching it through a nebuliser tubing to a mechanical compressor such as the DeVilbiss 5650, 4650, or 3655 series compressors, or compressed air or oxygen, set to permit 5-7 lbs. pressure or a flow of 6-8 L/min which will yield a nebulisation rate of 0.15 – 0.35 ml/min with a MMAD of 5 microns. In the past it has come under scrutiny especially with regards to the variability<sup>9</sup> of the outputs and the flow rates required to yield the 0.13ml/min nebulisation rate as recommended by ATS/ERS guidelines. Table 1. shows data for the DeVilbiss 646 at a flow rate of 7 and 7.5 L/min. At these recommended flow rates, the output using 0.9% saline is much higher than 0.13 ml/min. If the flow rate was reduced to produce 0.13 ml/min the particle size would be higher than 5-6 microns based on this data.

#### **FLOW RATE: 7 LPM**

Test Solution	Run #	Neb Sample #1 MMD	Neb Sample #2 MMD	Neb Sample #3 MMD	AVERAGE MMD
0.9% Saline	1	5.61	5.97	5.41	-
0.9% Saline	2	5.63	6.08	5.34	-
0.9% Saline	3	5.55	5.92	5.34	-
<b>Average MMD</b>		<b>5.59</b>	<b>5.99</b>	<b>5.36</b>	<b>5.65</b>

#### **FLOW RATE: 7.5 LPM**

Test Solution	Run #	Neb Sample #1 MMD	Neb Sample #2 MMD	Neb Sample #3 MMD	AVERAGE MMD
0.9% Saline	1	5.83	5.24	5.31	-
0.9% Saline	2	5.61	5.21	5.16	-
0.9% Saline	3	5.44	5.21	5.16	-
<b>Average MMD</b>		<b>5.62</b>	<b>5.22</b>	<b>5.21</b>	<b>5.35</b>

Flow Rate	Average Output of Nebs Tested
7.0 LPM	0.293 g/min
7.5 LPM	0.347 g/min

Table 1. Data supplied by DeVilbiss



**Table 2—Droplet Size Distributions for Eight Ultrasonic and Eight Jet Nebulizers\***

	Ultrasonic	Jet (6 L/min)	Jet (12 L/min)
<b>MMD (<math>\mu\text{m}</math>)</b>	<b><math>5.4 \pm 0.1</math></b> (4.8-6.0)	<b><math>6.0 \pm 0.3^\dagger</math></b> (4.5-7.0)	<b><math>3.7 \pm 0.2^\ddagger</math></b> (3.3-5.1)
<b>Percent of mass <math>&gt;10 \mu\text{m}</math></b>	<b><math>7.6 \pm 0.6</math></b> (5.3-10.5)	<b><math>13.9 \pm 3.8^\dagger</math></b> (2.3-25.8)	<b><math>4.3 \pm 2.0</math></b> (0.5-13.4)
<b>Percent of mass 5-10 <math>\mu\text{m}</math></b>	<b><math>46.7 \pm 1.0</math></b> (42.2-52.3)	<b><math>46.1 \pm 2.6</math></b> (40.7-50.8)	<b><math>29.2 \pm 3.1^\dagger</math></b> (22.6-37.5)
<b>Percent of mass 2-5 <math>\mu\text{m}</math></b>	<b><math>44.6 \pm 1.6</math></b> (36.3-50.7)	<b><math>30.6 \pm 4.2^\dagger</math></b> (23.4-42.9)	<b><math>42.9 \pm 3.7</math></b> (32.5-49.8)
<b>Percent of mass <math>&lt;2 \mu\text{m}</math></b>	<b><math>1.1 \pm 0.1</math></b> (0.7-1.5)	<b><math>9.4 \pm 1.3^\ddagger</math></b> (7.8-14.1)	<b><math>23.6 \pm 2.7^\ddagger</math></b> (16.6-27.1)
<b>Percent of mass <math>&lt;5 \mu\text{m}</math></b>	<b><math>45.7 \pm 1.4</math></b> (37.2-51.8)	<b><math>40.0 \pm 2.8^\dagger</math></b> (31.3-57.0)	<b><math>66.5 \pm 3.4^\ddagger</math></b> (49.1-76.9)

\*Ranges for these variables are given in parentheses (mean  $\pm$  SEM).  
p values compared to ultrasonic.

$^\dagger p < 0.05$ .

$^\ddagger p < 0.01$ .

Table 2 Taken from Newman SP, Pellow PG, Clarke SW. In vitro comparison of DeVilbiss jet and ultrasonic nebulizers. Chest 1987;92(6):991-994. Shows MMD and droplet size distribution of the DeVilbiss 646 Jet nebuliser when used at two contrasting flow rates.

## CALIBRATION AND OUTPUT CHECK OF A JET NEBULISER

The ATS Guidelines for Methacholine and Exercise Challenge Testing-1999 instruct that the nebulizer must deliver an aerosol with a particle mass median diameter (MMD) between 1.0 and 3.6 pprn [e.g. the English Wright nebuliser (Roxon Medi-Tech, Montreal, PQ, Canada) generates particles between 1.0 and 1.5 MMD. Furthermore they instruct to adjust the flowmeter to deliver the output established during the calibration procedure ( $0.13 \text{ ml/min}$ ,  $\pm 10\%$ )<sup>10</sup> ERS guidelines state that: *As the driving pressure and the flow rate of compressed air to a nebulizer increases, the aerosol*

*output increases and the resultant increased dose provokes greater airway narrowing. Therefore, all nebulizers must be calibrated to operate at a known output. The calibration needs to be performed under exactly the same conditions as those under which the system is used during a challenge test.*

For the tidal breathing method, the results are expressed in terms of concentration ( $\text{PC}_{20}$ ), and, therefore, nebulisers are adjusted to give a standardised output. The actual output is regularly checked at the calibrated value of airflow. This is adequate for most clinical and research purposes. However, weighing makes no allowance for evaporation of water during nebulisation.



Since the Wright nebuliser is now obsolete, the majority of centres have switched to an alternative nebuliser such as the DeVilbiss 646. We have used such an alternative extensively in our bronchoprovocation studies and have noted through regular output checks that the flow rate required to achieve a 0.13ml/min output is usually between 4 -5.5 L/min. This is

below the recommended flow rate by the manufacturer (6-8 L/min). Furthermore, on observation this output was frequently achieved despite a clear lack of proper nebuliser function.

**Table 12: Output characterisation of DeVilbiss 646 nebuliser using Gas Cylinder at a flow rate of 7 L/min**

	Weight of nebuliser (g)			Output (g)			Mean output / 2min (g)	Output (mL/min)
	n=1	n=2	n=3	n=1	n=2	n=3		
pot 1	51.424	51.417	51.368	0.000	0.000	0.000	0.000	0.000
pot 1	51.030	50.966	50.917	0.394	0.451	0.451	0.432	0.216
pot2	51.271	51.394	51.416					
pot2	50.837	50.985	51.018	0.434	0.409	0.398	0.414	0.207
pot3	51.961	52.198	52.053					
pot3	51.492	51.689	51.476	0.469	0.509	0.577	0.518	0.259
pot4	51.530	51.437	51.631					
pot4	51.100	51.000	51.220	0.430	0.437	0.411	0.426	0.213
pot5	51.747	51.909	51.812					
pot5	51.335	51.525	51.418	0.412	0.384	0.394	0.397	0.198
<b>Mean</b>								<b>0.219</b>

Table 3. Data obtained at Quintiles Respiratory Laboratory Demonstrated output values for NaCl- obtained using the gravimetric method for 5 DeVilbiss 646 nebulisers powered by medical air at a flow rate of 7l/min. This small dataset demonstrated outputs comparable albeit slight lower to those stated by the manufacturer as well as acceptable inter pot variability in nebulisation rate. It has been suggested that the well known variability in the output of the DeVilbiss 646 nebuliser may have arisen as a result of using these nebuliser pots outside of the recommended flow rate in order to achieve the 0.13 ml/min nebuliser output

### Effect of Evaporation on Nebulisation Rate

As already mentioned in the previous section the simple gravimetric method for determining nebuliser output fails to take into account the substantial effect of evaporation. It is widely accepted that there is considerable, although predictable, variability in the output of these nebulisers, where the evaporation may account for 30 to 40% of the change in weight suggesting that the gravimetric testing of nebulisers overestimates aerosol generation and thus makes calibration within  $\pm 10\%$  difficult. Our observations suggest that mean

weight loss increased approximately linearly with airflow rate through a DeVilbiss 646 nebuliser. Figure 1 (overleaf).

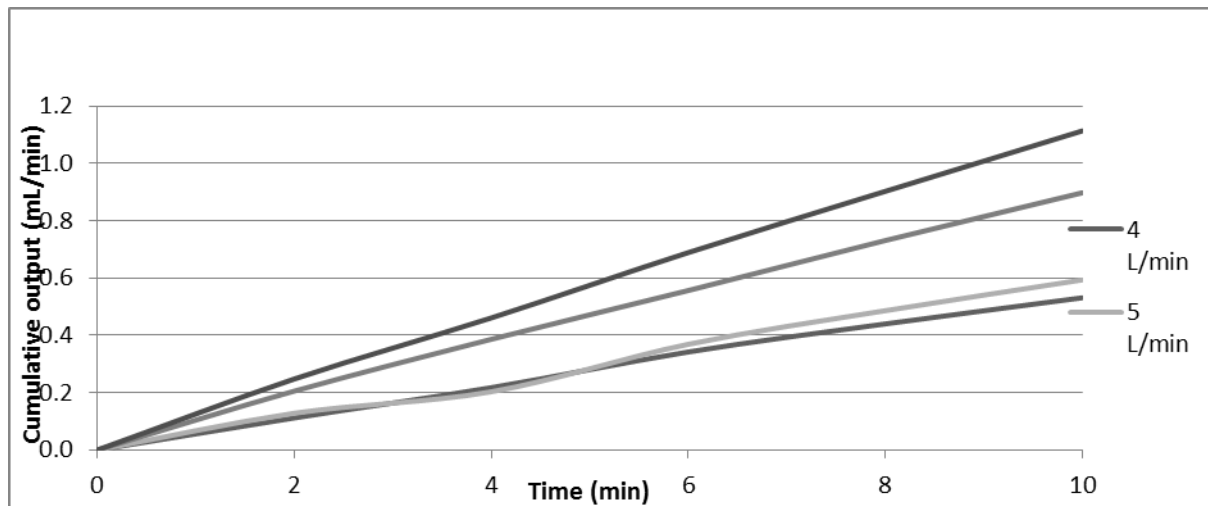


Figure 1. Cumulative output (mL/min) of DeVilbiss 646 nebuliser using Gas cylinder at different flow rates: 4, 5, 6 and 7 L/min.

Using the Wright Nebuliser Dennis et al noted that there was a threshold flow rate, near 7 L/min, below which aerosol output was negligible (Figure 2). These findings highlight the significance and shortfalls of using the gravimetric method for standardising nebuliser function.

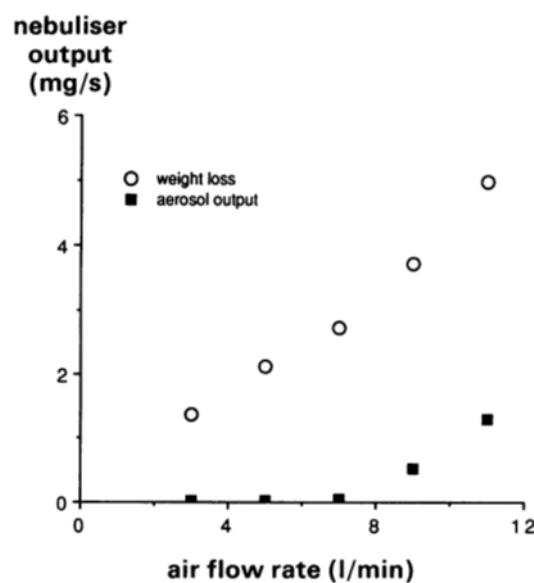


Figure 2. Effect of air flow rate (l/min) on rate of weight loss (mg/s) from a Wright jet nebuliser. Simultaneous measurements of weight loss and aerosol output over 20 second activation periods at flow rates of 3, 6, 9 and 11 l/mi were made in triplicate, from which mean values were calculated

### Particle size and driving pressure/flow

The amount of drug entering the lungs is critically dependent on the particle size distribution of aerosolised drug. Particles less than five microns in diameter are considered ideal for lung deposition, while larger particles tend to deposit in the upper airway<sup>18</sup>.

It is well accepted that the mass median diameter of aerosol droplets generated by a nebuliser are strongly influenced by the driving flow rate of compressed air. By increasing the flow rate from 4 to 8 L/min mass median diameters were halved ( $p$  less than 0.01) and there was an

increase in the mass of aerosol within the optimum respirable range (less than 5 micron)<sup>19</sup>.

Pressure kPa	flow rate	2.5ml fill volume		5ml fill volume	
		MMAD	%<5µm	MMAD	%<5µm
59	3	10.1	16	9.1	20
62	3.6	10.2	21	10.1	22
96	3.8	7.5	30	8.4	24
67	3.9	6.6	35	6.7	35
99	4	10	21	9.5	22
135	4.1	6.5	36	6.2	39
79	4.2	7.6	28	6.6	36
113	5.1	5.9	42	6.3	38
90	5.6	4.7	55	5	50
71	5.7	6.8	35	6.9	35
90	5.8	6.1	39	6.1	39
92	5.8	4.5	57	4.2	59
121	6.2	4.3	59	4.3	58
110	6.2	4.7	54	4.5	56
127	6.4	4.3	60	4.3	60
105	6.7	7	39	5.4	48
126	6.8	4	61	4.1	61
104	6.9	3.9	62	4.1	60
126	7	4.1	61	4.2	59
185	7	2.6	82	2.6	83
132	7.2	4.9	51	5	51
145	8	4.3	58	4	61

Table 4. Adapted from E.C. Smith, J. Denyer, and A.H. Kendrick (1995).[15] Demonstrates pressure and flow rate at the nebulizer, the MMAD and the percentage of particles less than 5.0 µm at a fill volume of 2.5 and 5.0 µm. .

Aerosols produced by medical nebulisers are usually heterodisperse – meaning that they are made up of different sized particles. However it is well documented that the driving pressure or flow rate alters the characteristics of the nebulised aerosol by altering the particle size. Smith et al (1995) demonstrated this (Table 4) and deduced that from a range of nebuliser/ compressor combinations in order to produce an MMAD of 5.0 µm or less, a flow rate of 6.3 L/min at the nebuliser is required. Furthermore they recorded that the relationship of flow rate to MMAD is independent of fill volume<sup>15</sup>.

It is widely accepted that the respirable range

for particle MMAD is <5microns. Larger particles (5–100 µm) are principally deposited in the nasopharynx, whilst particles of less than 5 µm will be predominately deposited in the lungs, including alveolar deposition. Particles that are less than 0.5 µm will reach the alveolar region with around 15% of the drug delivered being deposited<sup>2</sup>. This is because the method of deposition in the lung is due to gravitational effects, and the small size of the particles means that the time taken for the drug to deposit in any larger quantity is actually longer than the breathing cycle, and, therefore, the majority of the drug will be exhaled again.

As we already mentioned, the current practices

are based around the original work of Cockcroft et al where aerosols were generated in all cases by the same Wright nebulizer with 5 ml of test solution in the nebuliser container and an oxygen flow of 7 L/min. Under these conditions the nebuliser produced 0.13 ml aerosol/min with a particle size of 1-3  $\mu\text{m}$  mass-median diameter and a geometric standard deviation of 2.11. As we know particle size matters and such a small particle size may not be optimal.

Of significant interest are the findings of Naji et al<sup>3</sup>, who noted significant alterations of  $\text{PC}_{20}$  based on different particle size. The pairwise differences revealed a  $P < .001$  between 3  $\mu\text{m}$  and 1  $\mu\text{m}$  and between 5  $\mu\text{m}$  and 1  $\mu\text{m}$  and a  $P = .008$  between 5  $\mu\text{m}$  and 3  $\mu\text{m}$ . With the smallest particle size generated by the Wright Nebuliser (as used by Cockcroft MMAD, 1.0  $\mu\text{m}$ ) results in higher  $\text{PC}_{20}$  values ( $\text{PC}_{20}$  of 6.32 mg/mL) vs Aeroneb (MMAD, 5  $\mu\text{m}$ ) nebulizer had the lowest  $\text{PC}_{20}$ , with a  $\text{PC}_{20}$  of 0.62 mg/mL

These findings suggest that larger particles within the respirable range may have the greatest effect.

If we can assume that a 10  $\mu\text{m}$  diameter drug particle contains the same amount of drug as 1000 particles of 1  $\mu\text{m}$  diameter thus describing the number of a certain size may therefore give a much distorted view of the mass of respirable drug/challenge agent obtained from a nebuliser<sup>4</sup>. This further highlights the importance and significance of an optimum particle size with respect of its potency and area of deposition within the bronchial tree, and throws into question the effectiveness and efficiency of the Wright Nebuliser as used by Cockcroft.

Studies on segmental bronchial reactivity and constriction show that airway size plays an important role in the maximum response of airway narrowing, with small airways showing closure and large airways a plateau<sup>6</sup>. P.R. Gray, H.W. Mitchell (1996) demonstrated a clear relationship between airway size and sensitivity to acetylcholine and a significant correlation between airway diameter and  $\text{pD}_2$ , which translated to an approximately 160 fold difference in responsiveness between the 1.2 and 5.5 mm diameter groups<sup>5</sup>.

We already know that there are variations in the structure and receptor availability in the airway and that reactivity in vivo can be attributed to receptor distribution or airway wall mechanics, however here we attempt to address the differences in aerosol deposition which is directly affected by the delivery method.

### Allergen Concentration calculation derived from the Cockcroft equation

One of the reasons for the majority of studies and recommendations quoting the 0.13 ml/min nebuliser output are that the prediction equations are method specific<sup>11</sup>. For the derivation of the equations relating to allergen dose selection (in combination with skin prick testing), histamine/methacholine and allergen inhalation were conducted by using identical methods, namely 2-minute tidal breathing from a jet nebuliser with an output of 0.13 ml/min. It is understandable why so many researchers are reluctant to stray from this recommendation. We feel that, in the light of a wider meta analysis, this does not provide scientifically sound rationale since different nebulisers may require different flow rates in order to achieve

this output. Hence allergen or methacholine would have been delivered in different particle sizes, deposited differently and thus affecting the PC<sub>20</sub>.

A formula to predict the allergen concentration required to produce an EAR (i.e., allergen concentration causing a decrease in FEV<sub>1</sub> of 20% from baseline) has been developed based on skin prick test end point and PC<sub>20</sub> (histamine/methacholine) values<sup>12</sup>.

In the light of these findings and proposed changes to the use of the jet nebulisers based on particle size and not the output, one must also address the other aspect of the equation, which is the skin prick test and potentially standardise this method since this may lead to differences in wheal diameter following skin prick allergen testing<sup>13</sup>. Statistically significant differences in wheal diameter have been noted between two commonly used methods- standard lanced method and Duotip test 2 (Lincoln Diagnostics plc)<sup>14</sup>. Historically the Cockcroft skin prick test required a 10-minute

waiting period for the wheal to develop<sup>21</sup>.

More recent EACCI recommendations state that a 15-minute period would be used<sup>20</sup>.

Could it be that, by not allowing sufficient time for skin wheal to develop, one was effectively overdosing a patient with allergen as a smaller wheal would deem that patient less sensitive?

Based on this equation higher PC<sub>20</sub> values along with small atopic skin reactions to allergen testing yield greater allergen concentrations where as the patient is deemed to be less sensitive. We must thus address the impact of more efficient methacholine delivery, potentially leading to lower PC<sub>20</sub> values, as well as using the most consistent and predictable skin prick testing method.

This topic requires further research with regards to the effect of better methacholine or allergen delivery through correct usage of a nebuliser as well as the effect of the SPT method on the generation of inhaled allergen dose range.

## CONCLUSION

This very brief and simplistic meta-analysis highlights the potential pitfalls of standardising inhaled challenge method to the widely accepted 0.13L/min output of a jet nebuliser. It does not address more complex variables such as breathing frequency, viscosity, suction flow rate or the bronchial segmental differences in airway architecture or receptor levels, concentration, jet pressure, and evaporation. All these parameters can influence the output of the nebulizer<sup>8</sup>. Tuning the flow rate/driving pressure to achieve the recommended nebuliser output of 0.13ml/min may lead to significant shifts in the particle size produced by the nebuliser, their deposition and therefore the outcome of a bronchial challenge test.

Whereas there is good rationale for following a standardised method of bronchial challenge protocols, such as those outlined by Cockcroft et al and by specialist bodies, as it allows direct comparison between studies, one must address whether the current methods contained within these protocols truly reflect the physiology of the patient. Is the PC<sub>20</sub> in fact altered by nebuliser performance? Are the skin prick tests influencing the Cockcroft equation and thus allergen dose for inhalation?

With regards to what this document is aiming to address as a primary topic: the particle size and drug/challenge agent deposition should be of primary importance and a focal point of method standardisation for tidal breathing nebulised challenge agents. Until laboratories have access to measurement systems such as laser diffraction to measure particle size and distribution, the sensible approach is to follow the manufacturers' recommendations for their devices.

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Nigel Clayton  
Brendan Cooper

# ON THE BLOWER

Just after you thought I had departed as Chair of Manufactures Liaison, I am back again (albeit temporarily), covering for Stuart Wragg who has temporarily had to step back from the role. In a much shortened version of On the Blower we have the usual company round up, details of a campaign to fast track CPAP treatment for vocational drivers and a report on EU Legislation on Medical Devices.

In the absence of Stuart it is recognised that we will need an interim Chair for Manufacturers Liaison. If you feel you could fulfil this role and would like to apply for the position, or know of anyone who would make an excellent ARTP / manufacturer representative, please contact me ([nigel.clayton@uhsm.nhs.uk](mailto:nigel.clayton@uhsm.nhs.uk)) and I will pass the details to the ARTP board. I will of course continue in the role as long as necessary to allow time for the successful interim chair to shadow and develop in the role with additional support from Brendan and Alan. As and when Stuart is back as chair, it is expected that the interim chair will continue to deputise for Stuart.

## RESPONSE TO 'BAYWATCH' ARTICLE, INSPIRE 15:3, p33

Baywater Healthcare has been working in partnership with the NHS for over 10 years delivering high quality, homecare services. Like many other private sector providers, our aim is to complement the excellent work of the NHS through the management of medical equipment and the provision of clinical support.

We are committed to working in partnership through services such as home diagnostic studies, the provision of CPAP equipment and patient adherence programs, we help ensure patients are as comfortable as possible with the therapy prescribed by their sleep specialist. The addition of this type of support, delivered by a qualified, experienced team, is ultimately aimed at enhancing the patient experience and improving outcomes. Our clinician and patient satisfaction surveys are testimony to the quality of our service and the results we deliver.

Baywater has been an active supporter of the ARTP for a number of years and we have sponsored both the national conference and the Strategy Meeting. We very much hope to build on that relationship. By working together I believe we can achieve much more and that will benefit patients.

I would welcome the opportunity to discuss how we can further support the work of ARTP members. **Adam Sullivan, Chief Executive**

## CAREFUSION

As mentioned in the last edition of Inspire, Becton Dickinson & Co. has purchased CareFusion Corp. in a \$12.2 billion deal. Stuart Bennett, the UK Sales and Marketing Manager, has been in contact recently to offer assurances that there will be no significant changes in the UK PFT market and that to date Becton Dickinson has not made any significant noises to change the way the PFT side of the business operates. New appointments have been made within the company to ensure continued service support. Shafiq Siddique has recently

joined the company as UK Customer Support Manager and I have been told that he will be out on the road meeting customers and listening to what we expect in terms of customer support and service. CareFusion has also announce the appointment of Travers Barr as Account Manager for London and the South East and William Downey as the new field based Customer Support Team who will be based in the North West and serving the surrounding areas.

NC

## PHILIPS RESPIRONICS

Following on from their success in winning the ARTP manufacturers award for best sleep company 2015, Philips Resironics has just announced their latest range in CPAP interfaces. CPAP interfaces have developed significantly over the last 15 years with the ultimate aim to improve comfort and therapy compliance. As we all know, compliance in the younger age range is always a problem, with CPAP being viewed as "Uncool". Philip Resironics has focused on the younger age range and has just released the Wisp Youth CPAP interface. Designed for use in patients weighing as little as 18kg (approximately 7 years), it offers comfort with minimal design to help the smallest

patients achieve long-term compliance. It achieves this with an open field of vision so that children can wear glasses to read bedtime stories or watch TV easily. Each Wisp Youth package comes complete with three cushion sizes, designed to fit more than 97% of children.

The Philips Resironics PAP travel briefcase is designed to make travelling with sleep therapy equipment easy and convenient. Two separate bags combine into one so that patients have just a single carry-on for their therapy equipment, laptop and other travel items.

NC



## RESMED

After many years at the helm Ross Sommerville has moved on to pursue personal projects, although he will continue to act as a consultant to ResMed both here and in Europe, so don't be surprised if you should see him out and about. Ewan Cuthbertson, the Commercial Manager, has now taken over the reins of Managing Director. Ewan has been with ResMed for over two years. A pharmacist by training, his career has included roles both within and serving the NHS. A new Commercial Manager will shortly be recruited to replace Ewan. Another personnel change is the departure of John Mitchell from the North West. John is being replaced by Colin Irvine who will start to get "out and about" in April. If unsure of who to contact during the changeover period, contact ResMed at [operationsuk@resmed.co.uk](mailto:operationsuk@resmed.co.uk).

On other matters, the countdown continues to the conclusion of the Serve-HF clinical study, evaluating the impact of PaceWave adaptive servo ventilation in reduced ejection fraction heart failure patients with predominantly

central sleep apnoea. There will be a new international congress in Paris in April aptly entitled CardioSleep which demonstrates the level of interest building in the heart failure community for both the results of the study but also to further understand the interaction between the heart and breathing disorders.

This Spring ResMed will be launching "myAir", a new personalised therapy management application for patients with sleep-disordered breathing. myAir equips patients with the information they need to resolve basic therapy issues so they can increase their comfort and stay compliant. Patients can access myAir from their mobile phones and tablets, anytime, anywhere. The platform has been designed exclusively for ResMed's AirSense™ 10 and AirCurve™ 10 devices, both of which are wirelessly enabled to automatically deliver therapy data into myAir on a daily basis. NC

## MEDICAL GRAPHICS UK



Following on from winning the ARTP manufacturers award for best respiratory company 2015, Medical Graphics has just announced the latest version of the Ultima Series™ Cardiorespiratory Diagnostics system. This now features a fully adjustable desktop for use in the sitting or standing position, room-to-room portability with gas tanks and an optional on board uninterruptible power supply (UPS) and automatic power saver to ensure the system is automatically powered up prior to the start of the day. NC

## SLEEP APNOEA TRUST – PRESS RELEASE

A campaign has been launched that aims to reduce the number of deaths and serious injuries on UK roads by calling for fast-tracked medical treatment for vocational drivers who have obstructive sleep apnoea syndrome (OSAS). The campaign has been launched by the OSA Partnership Group, a collective set up to raise awareness of the condition. The Group calls on the Department of Health to issue guidance to Clinical Commissioning Groups (CCGs), hospitals and GPs to expedite treatment of vocational drivers with OSAS to enable driving again within a maximum of four weeks following first referral. Obstructive sleep apnoea syndrome (OSAS) is particularly common amongst middle-aged men, especially those who are overweight. Studies have shown that when a driver with untreated OSAS gets behind the wheel of a vehicle, they are between 3 and 9 times more likely to have an accident and that this accident is likely to be of increased severity. Professor John Stradling, a member of the OSA Partnership Group and author of the campaign paper, has spent his career working with sleep apnoea patients as a respiratory consultant in Oxford. He says, "In my experience vocational drivers are often the safest on our roads but those with OSAS have no control over their sleepiness. We also know that these drivers are reluctant to come forward with symptoms of OSAS for fear of losing their licence, and therefore their livelihood. "Through the collaborative work our Group has undertaken with the transport industry, we believe that by expediting treatment, we can reduce this fear and therefore encourage drivers to get the treatment that will allow them to drive safely (and considerably benefit their quality of life). In doing so, we can eliminate many unnecessary road traffic accidents, and ultimately reduce the number of serious injuries and fatalities." The most usual treatment for OSAS is Continuous Positive Air Pressure (CPAP). Indeed in 2008 NICE carried out a technology appraisal that said that CPAP should be available to all who required it but it did not give a timescale for supply, and as a result this varies widely across the UK from a few weeks to several months. Yet it is the uncertainty as to how soon they will be treated that stops many drivers coming forward. Bill Johnston, Chairman of Sleep Apnoea Trust (SATA), a member of the OSA Partnership Group says, "We believe that this campaign will provide drivers and their employers with a clear indication of how long a driver can expect to be off the road and therefore enable contingency plans to be put in place, The alternative, particularly in light of the growing prevalence of sleep apnoea, is to risk an increase in road traffic accidents and more deaths on our roads." RAC Business, which has recently joined the OSA Partnership Group, also recognises the significance of the campaign. Jenny Powley, RAC Business Corporate Sales Director, said: "This is an incredibly important initiative as OSAS is a condition which has no respect for the great skill and experience of the drivers it can affect. Although we know an average HGV driver completes many miles every year without incident, if they do have an accident it can often be much more damaging than a smaller vehicle such as a car, due its size and bulk. "In the long term business as a whole will benefit as drivers who suspect they may be suffering



from OSAS will be able to get the treatment they need and be back on the road much more quickly, which is a better outcome for the business owner, fleet manager and everyone concerned.” Professor Stradling concludes, “We have spoken to a number of clinicians and sleep clinics, all of whom have agreed that vocational drivers can, and should, be treated within this time period. We would now ask the Department of Health to support our call and to put this into action in order to save the devastating cost of accidents caused by

untreated OSA patients.”

If you need more information please contact:

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NC

## EUROPEAN LEGISLATION- INTERFERENCE OR INSPIRATIONAL: A REPORT FROM THE EASD/ERS SUMMIT ON MEDICAL DEVICES LEGISLATION—DR BRENDAN G. COOPER

*As we go to press, we are being bombarded by the General Election political bun-fighting over many issues, but in this election, “Europe” is being highlighted as one of the key battlegrounds. However, in our respiratory physiology world, where or how does the EU affect our daily work?*

I was recently asked by ERS to attend a European Summit on EU Legislation on Medical Devices and present how it affected respiratory medicine. This article will briefly outline some of the key issues which impact on our respiratory physiological services.

### Key features of new EU Medical Devices Legislation

The EU defines a Medical Device as ;

*“any instrument, apparatus, appliance, software, material or other article that is intended to be used for the purposes of (where appropriate) diagnosis, prevention, monitoring, treatment, alleviation or compensation of a disease, or an injury or a handicap. “*

In 1985 the European Council defined the ‘**New Approach**’ to Medical Devices Legislation which introduced an innovative methodology of technical harmonisation designed to remove barriers to trade and facilitate the free movement of goods with the European Union.

The principle of the new approach was the installation of **Notified Bodies** which are organisations accredited by a member state (in the UK this is the BSI and MHRA) to assess whether a medical device meets relevant regulatory requirements in the EU. A series of EU Directives were then added as amendments in the following years.

Additionally, the Commission recommendation released in April 2013 on the unique device identification system (**UDI**) System should be considered:

*COMMISSION RECOMMENDATION of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union to enhance the traceability of medical*

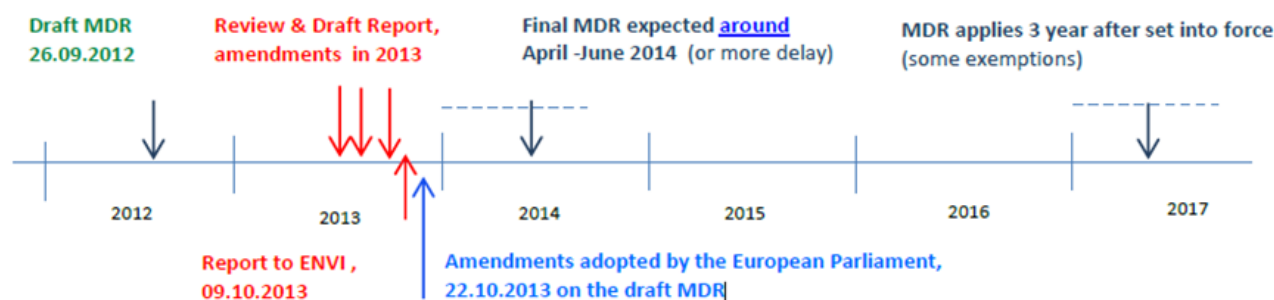


devices throughout the whole supply chain contributes to patient safety by facilitating vigilance, market surveillance and transparency in this sector (9.1).

### Key Features of Legislation

- Notified Bodies
- Overhaul of system (complicated)
- Pre marketing clinical investigation
- Post marketing surveillance
- Change of regulations required –critical analysis

**Figure 1. MDR Recast – Timelines for Implementation**



### Implications of Legislation for ARTP members.

The 3 parts to the EU medical devices legislation, MDD, AIMDD and IVDD covers the broad range of respiratory medicine and has implications for most Respiratory Medicine Departments. Examples of the types of devices in each category are shown in the table;

Medical Devices Directive (MDD; 93/42/EEC),	Active Implantable Medical Devices Directive (AIMDD; 90/385/EEC)	In Vitro Diagnostic Medical Devices Directive (IVDD; 98/79/EC).
Nebulisers	Diaphragm pacing devices	Blood gas monitors
Spirometers	OSA nerve stimulators	Blood composition analyzer
X-ray machines	Airway valves	Genetic testing?
CPAP machines		Clinical Chemistry

There is further complication into the “Class” of device as to which part of the legislation they are covered by. This classification is covered by the European Union (EU) and European Free Trade Association (EFTA):

Annex IX of the Council Directive 93/42/EEC. There is a complex flow-chart of how a device fits into a class, but generally, the algorithm is sensible and appropriate for most devices. The classes are summarised in the table below;

CLASS	RISK	EXAMPLES
I	Low	Sticking plasters, corrective glasses
Ila	Med-Low	Tracheal tubes, dental filling material, CPAP
Ilb	Med-High	X-ray machines, bone plates and screws, Non-invasive ventilators
III	High	Heart valves, total hip replacements, breast implants, airway valves
III	AIMDD	Diaphragm pacemakers, implantable defibrillators

There is a need for more transparency around pre-market testing and post product release vigilance of new products, and market surveillance is paramount if patients are to be protected from harm. This pre & post market control, provided it is flexible, safe and rapid would allow access of new innovation, after being assessed and validated clinically and scientifically to patients. Continual monitoring of equipment performance using on-line digital feedback (e.g. EUDOMED, MAUDE) will accumulate knowledge and should flag up failures and risks to patients

In case you weren't aware, just like there is a centralised system for problems with medicines (side-effects, untoward events, etc.). EUDOMED is a website that collects this data for European medical devices (MAUDE is the US equivalent), but is grossly underused. Have you ever had a problem with a medical device and wanted to report it to someone (other than ARTP Watchdog!)? Well, there is a route out there.

There is concern that if a “EuroFDA” (like the U.S. FDA) was set up it would slow innovation and bringing new products to the patient, however the current financial climate would make this unlikely in the foreseeable future.

## Medical Smartphone Apps

All medical devices are highly regulated, but computer applications (Apps) have very little regulation. The FDA in 2013 considered Apps and concluded that if an App facilitates communication between a medical device and a Smartphone (e.g. Blood pressure monitor and a mobile phone) then there needs to be guidelines around this. They decided that Diet and Exercise information only Apps would be exempt. However, an insulin dose App based on a glucometer reading is likely to be regulated. There must be potential for respiratory Apps falling under this category. Possible apps could be used in asthma, oxygen therapy, non-invasive ventilation, CPAP, symptoms scores, etc.

It must be considered that with the fast pace of App development, the gradual melding of lifestyle/medical and consumer/clinician functionality, and the great prospect for innovation, this area may become fraught with difficulty. The European regulations need to address this issue.

I learned that the European Commission on EU Medical Devices Regulation has only 12 members of staff in the Medical Devices Commission to cover all medical regulation! They are responsible for the devices healthcare and business and believe that the drivers for change in medical devices stem from (i) technical & healthcare developments, (ii) globalisation of products, (iii) public expectations from exposure to the internet & (iv) the PIP (breast implant) scandal.

The transition to the new EU Medical Devices legislation will take 3 years for medical devices and 5 years for IVDs, because the processes and relationships between EU Parliament, EU

Council and EU Commission is complex. Unfortunately, just like after a change of government in the UK, the processes will take a while to start and the EU Parliament changed last year (unfortunately, UK is represented by individuals who don't like Europe), so we may all lose out on influencing any change!

There was mention of the possibility of reprocessing of single use devices. All devices considered suitable for reprocessing would be treated as "new devices" initially, but member countries would be able to ban reprocessing if they wished. Re-processors will have to provide safety/scientific evidence before being accepted. This may have implications for MDI spacers in the respiratory world.

Another speaker was John Brennan, who is the Director of Regulations & Industrial Policy at MedTech Europe who represent medical device manufacturers in Europe. He was concerned that the legislation pathway was behind schedule because of the PIP pathway and that there was too much debate and not enough action between the European Commission, Council and Parliament. (Something we are all aware of!).

He stated that whilst the IVDD Directive needs active debate, the MDD legislation is basically good. He also commented that the Notified Bodies need much more clinical involvement and that the system needed to ensure there was not double scrutiny in Council and Parliament and that transparency is vitally important. There needs to be more coordination of experts and relevant groups. The UDI process could begin immediately, if member states just chose to get on with it. He reviewed briefly the Dutch US/Europe legislature and concluded that

both systems do the same thing, both trying to improve safety and accountability. The FDA appear to be going more European, as Europe begin to act more like the FDA . A middle ground is required between these two approaches.

The FDA has a surveillance system MAUDE which collates FDA medical device reports (MDR) of suspected device related deaths/serious incidents. It has enabled reporting of adverse events more easily and effectively. The FDA are setting up a task force to address the issues raised around addressing patient safety issues and good post-marketing surveillance

There was a powerful presentation on E-Health from Kelly Close who runs an influential patient group (Close Concerns) for diabetics in USA. She explained how technology has

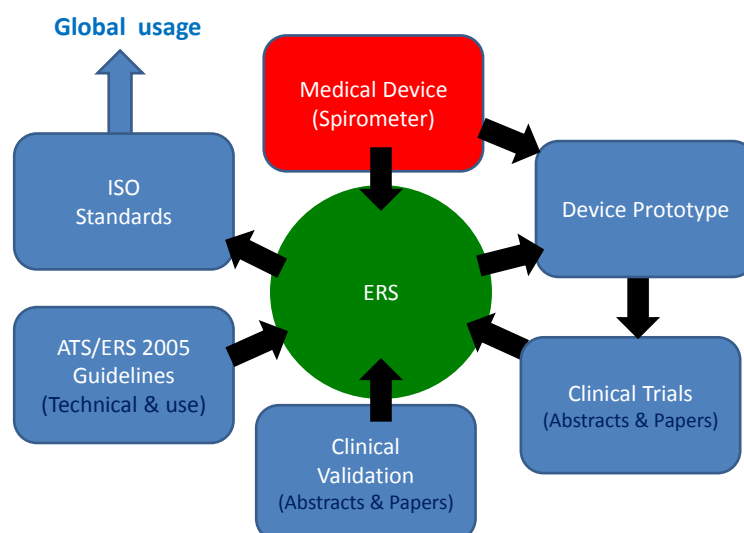
moved forward and that E- Health is fast developing. There was no E-Health in 1985 and this has already grown to 30million users today and it is projected that by 2035 there will be 590 million users! She emphasised that connectivity is more important than pumps and analogue insulin! Devices change patients lives, but the patient, provider and system all face challenges on this.

She went on to explain that with decreased clinical time with patients, and increasing prevalence of disease and decreased financing of health there was a “perfect storm” developing. Her organisation gets patients/ clinicians to “Road Test” medical devices. This is something that ARTP should seriously consider doing and would be a good focus for ARTP Watchdog in the future. Patient power will become greater in the future.

## ERS Experience of Medical Devices Legislation



### Setting Standards



The ERS is central in the role of the development of new medical devices and technology and the example of how ERS has obtained ISO Standards for peak flow meters

and spirometers is a good example of using medical device legislation. (see “Setting Standards” figure)

The work done by Prof Martin Miller (ARTP

Award Winner, 2012) through ERS on peak flow meters showed how clinical science found the error in PFM scale, corrected it and used this evidence to implement the EU standard EN 13826:2003 (2003) and later the ISO Standard EN ISO 23747:2007 (2007). This was further backed up in the 2005 ERS/ATS published lung function testing guidelines which removed the concept of a 'low range' peak flow meter. (see References) All Wright scale products were consequently withdrawn from the market in 2004. The ISO standard became a worldwide standard, national notified bodies (British Standards Institution (BSI), Deutsches Institut für Normung (DIN), American National Standards Institute (ANSI) & other national standards bodies. This

standard applies to all peak flow devices (PFM or spirometer) so that the same 'peak flow' reading is obtained on all devices. The ISO issued a new standard in 2009 (ISO 26782:2009), which covers the essential technical operating characteristics and test methods for spirometer devices and software.

John Brennan (speaker from MedTech Europe) commented that the EU has backed away from ISO standards recently because of the excessive workload around MDD legislation. However, this is a mistake and pressure should be put on EU to re-engage with developing ISO Standards for Medical Devices. Andrew Boulton in his summary commented that the ERS example of using ISO Standards should be pursued.

## ERS Perception of EU Medical Devices Legislation

In my presentation I outlined the ERS perceived views on proposed EU Medical

Devices legislation and these are summarised in the following table;

PROS	CONS
Safer for patients	Safe & timely manner for new devices?
Centralised and standardised process	Stifle innovation?
Equality across markets	Current system 3-5 years earlier than FDA!
Encourage equipment validation and research	Delay unlikely to increase safety
More inspections, audits and monitoring	Detrimental to medical equipment market capacity
Better unique device identifier	

## Learning points for ARTP

- ARTP should consider raising medical devices legislation at the ARTP Manufacturer's Liaison and SAC meetings.
- ARTP need to engage more with manufacturer's and CAs about the legislation
- ARTP should contact ERS Brussels Office to investigate how ERS can influence the proposed changes to this legislation. Also ERS needs to consider collective approach with other Respiratory Societies (through FIRS, FERS) and other Professional Societies (EASD, ESC, etc.) to add weight to the arguments
- ARTP to consider publishing "road tests" on respiratory equipment from patients/clinicians and put on "Buyer's Guide" webpage.
- ARTP should publish articles on the issue of European Medical Device legislation and keep the membership informed about relevant issues in this area.

## Conclusion

This meeting has been a useful insight for ERS and ARTP in European Medical Device Legislation and from the learning points above suggested actions that should be taken.

**N.B.** *This article is an overview of a report that will be published by ERS in 2015. Copyright will be granted to ERS although content in this article will be exempt.*

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<sup>1</sup> Young et al. AJRCCM 2002; 165: 1217-39. ApneaLink is a trademark of ResMed Germany GmbH. © 2014 ResMed. Specifications may change without notice.





**And the winner is.....**

## **Manufacturers and suppliers survey report 2014/15**

**Compiled by Nigel Clayton**

10 years on and I am pleased to say we have yet another new winner in the respiratory equipment supplier category.....

The main players in the market may not have not changed significantly over the last 10 years, however their products certainly have. We also have many newcomers, particularly in the sleep market, snapping at the heels of the big boys desperate for market share. Competition is important and it is only by providing quality equipment and quality service that companies can survive in todays cash strapped NHS environment. The responses received in the survey certainly emphasise the importance of quality in training and service.

Towards the end of this report you will find a compilation of the survey scores accrued over the last 10 years. You will be able to judge for yourself which companies have improved and those which are failing.

*A big thank you once again to all those who took the time out to complete the survey questionnaire. In the survey we asked you to rate each company on a scale of 1-5 in each of the 16 sections listed below.*

### **Equipment**

1. Reliability
2. Ease of use
3. Running costs (including consumables)
4. Training given at time of installation
5. Overall quality of product

### **Sales**

6. Brochure information
7. Pricing policy
8. Flexibility on price of package
9. Demonstration
10. Knowledge of sales person

### **Service**

11. Ease of contact
12. Response time to rectify problem
13. Ability to resolve problem on first visit
14. Quality of service delivered
15. Attitude of service personnel
16. Punctuality of service personnel

As the years have gone by you have continued to provided an ever increasing amount of written feedback. It appears that positive comments once again outweigh the negatives, so well done to all companies concerned on achieving such great feedback. The following are excerpts from the positive survey comments.

- **Paul Griffiths** continues to be the valuable lynch pin with vast knowledge of these systems. He is always able to advise over the phone if necessary and able to come on site with efficiency – an excellent engineer. *(well done Griff – you will always be in the thoughts of the ARTP and those who knew you.* Ed. A tribute to Griff is at the end of this section) (**Vitalograph**)

- [Chris Ferrie](#) is a very knowledgeable and helpful engineer who goes out of his way to provide excellent customer service. ([nSpire Health](#))
- Very good service. Most issues resolved over the phone or using remote access system the company has. Very quick response and resolution of problems. ([nSpire Health](#))
- [Jim Horne](#) continues to provide excellent service cover, both for routine maintenance and any (rare) problems that occur. I can't praise them enough. ([nSpire Health](#))
- [Lynton Elcocks](#) is brilliant as our service engineer. ([nSpire Health](#))
- [Medical Graphics](#) have provided excellent customer service and have supported us greatly.
- The team did an excellent job of installing and networking the whole department in one full day. Lots of training and support were given to staff and the team were readily available until all staff were confident on the systems. ([MedGraphics](#))
- The equipment is very user friendly and easy to use, it has also been very reliable and we have had no problems with the system. [Oliver](#) has been extremely helpful and is very knowledgeable about the equipment and its capability. ([MedGraphics](#))
- Representatives have always gone out of their way to provide excellent support for the lung function market. ([CareFusion](#))
- [Darren](#) is very helpful and easy to get hold of whenever we have a problem. His knowledge is amazing. ([CareFusion](#))
- [Tim Kenny](#) and [Shaun](#) – excellent engineers. ([CareFusion](#))
- The member of the sales team ([Patrick Jamieson](#)) is always extremely helpful, supportive, knowledgeable and informative. [Darren Murray](#) is also very helpful and friendly. ([CareFusion](#))
- [Patrick Jamieson](#) requires particular praise for stepping into the breach and covering the entire UK. He is exceptionally knowledgeable in everything respiratory physiology, easily contactable and a pleasure to work with. ([CareFusion](#))
- [Mark McDonnell](#) is always very helpful and supportive. ([Love Medical](#))
- I love these spirometers! The software is intuitive to use, the patients find them easy to hold and the mouthpieces are a more natural shape and comfortable for patients. Infection risks are minimised by design. ([Intermedical / ndd](#))
- Absolute pleasure to deal with. If a problem can't be solved, replacement kit is provided immediately. Helpful and reliable company. ([Unahealth](#))
- Training and support from technical team is excellent, particularly [Peter Phillpott](#), [Emma Braithwaite](#) and [Ben Holdsworth](#). Always willing to provide support and service. ([ResMed](#))



- From sales to engineers – all extremely professional, helpful and go the extra mile. (ResMed)
- Hannah is always very helpful and goes out of her way. Easy to contact and receive quick responses. (ResMed)
- Attended several educational training packages that they have provided. All speakers extremely knowledgeable and good practical workshop session for developments and for new people starting in the field. (Philips Respironics)
- The sales rep Rory is always great to work with. Polite, can-do attitude and wants the best for his customers. Rachel is also very knowledgeable and always there to help with queries. (Philips Respironics)
- We would particularly like to mention Anwen and Phil for their outstanding service provided to the department this summer and Phil Pace for his prolonged support throughout 2014. (Philips Respironics)
- Company has given us replacement devices in the past while fixing faults with our units. (Aerocrine)
- Julian and team provide the very best service at all times. They have been invaluable when setting up our service. (Love Medical)

As always, we see many comments relating to poor service. Those that are printable are shown below. See if you can guess which companies they relate to.

- Service contracts are very, very expensive!
- Disappointed that there seems to be little progress made re GLI predicted values.
- Who ever bought this machine before I took up post here must have very little knowledge of equipment available.
- This equipment has had network problems on and off for about 3 years. Unfortunately the company cannot fix this issue as they don't appear to have the knowledge to do this, so disappointing.
- We have never had a visit from the sales rep. and when we have tried to get information regarding their machines and new masks we have to go through customer service. Our previous rep. never turned up or if they did, were never on time.
- Good quality results obtained from equipment however, numerous problems which are rarely resolved on the first visit. Problems more with software than hardware.
- The team have been very easy to contact, but have been slow to arrive. We have had to work a lot out for ourselves, but maybe this is due to our specifications and an ever changing research field.



- Some issues such as TLco faults appear to take 5+ months and require the lab to keep prompting for updates. Sadly this impacts on how the equipment is viewed.

#### AND THE WINNER IS .....

Before a company can be entered into the survey a minimum of 10 returns are required to help reduce any scoring bias. Unfortunately only two sleep companies met the criteria. For many years Medical Graphics has been on the verge of securing enough returns to be considered in the survey. Finally they have secured enough and have gone on to win the Respiratory Equipment Supplier of the Year award for the first time.

#### RESPIRATORY EQUIPMENT SUPPLIER TOP 4

1	Medical Graphics	72.80
2	nSpire Health	70.39
3	CareFusion	68.69
4	Medisoft (Vitalograph)	65.97

#### SLEEP EQUIPMENT SUPPLIER TOP 2

1	Philips Respironics	74.56
2	ResMed	68.63

FINAL SCORES OUT OF A MAXIMUM OF 80

The ARTP wishes to congratulate both Medical Graphics and Philips Respironics on winning this years awards. As always, both companies were thrilled to pick up their awards at the conference gala dinner.



Medical Graphics and Philips Respironics collecting their awards from Alan Moore, Nigel Clayton and Stuart Wragg

## MANUFACTURERS LEAGUE TABLE

	Medical Graphics	Medisoft	nSpire Health	CareFusion	Vitalograph spiros	Micro Medical	Philips Respironics	ResMed	Radiometer
2014	91.00	82.46	87.99	85.86	77.73	75.71	93.00	85.79	82.75
2013		80.60	90.00	85.70	80.30	77.50	91.70	88.10	86.50
2012		75.40	86.00	83.00	81.40	69.90	87.90	87.65	85.00
2011		79.34	84.06	77.29	81.47	74.18	83.13	88.59	86.08
2010		87.68	84.78	79.49	80.55	78.60	85.78	84.76	74.80
2009		83.56	85.89	73.85	80.91	73.78	86.09	86.62	80.48
2008		84.24	82.33	77.69	84.26	75.25	83.75	86.82	82.55
2007		83.00	84.10	75.60	79.80	74.00	78.10	86.20	87.20
2006		80.91	75.69	75.69	78.75	76.67	81.54	87.58	86.23

### The future

2015 may see changes in the way we run the survey to allow some of the smaller companies to gain recognition for the great work they do. Look out for an announcement later in the year!

Please direct any comments regarding the survey to ARTP Manufacturers Liaison:

[manufacturers@artp.org.uk](mailto:manufacturers@artp.org.uk)



### In memory of Paul Griffiths ("Griff")

As ARTP President and on behalf of all in ARTP, can I offer Griff's family and colleagues our sincerest condolences. I knew Griff well as our exercise equipment engineer for many years (and at Morgan Ferraris before that), and he was always the person who would find and solve the problem no matter how long it took. Indeed he was here sorting something out just before Christmas and we shared our usual banter, but we also had a mutual respect for each others professional integrity and knowledge. His contribution to our profession was valuable and I feel it will be very hard to replace him with his strong work ethic, amazing practical skills and dogged tenacity.

Other ARTP members have contributed their own memories of Griff's career via the ARTP Forum. We will all feel his loss at Conference this year as he was a true member of the ARTP "family".

Our thoughts and feelings go to his family.

Kind regards and deepest sympathy,

Brendan

President, ARTP

## Minutes of the 39th Annual General Meeting (AGM) of the Association for Respiratory Technology and Physiology (ARTP) held at the Hilton Hotel Blackpool on 22nd January 2014 at 15.40

*Dr Karl Sylvestre (KS), ARTP Honorary Chairman welcomed the audience that was in excess of 70 people and outlined the agenda for the AGM.*

### Review of 2014 Objectives

The key 2013 aims & objectives of the ARTP were reviewed and progress was reported as follows:

- Implementation strategy for GLI equations – in progress
- Decide most beneficial stakeholder membership of Respiratory Alliance – not required
- Finalise equivalence processes for members at STP levels - completed
- Finish/publish working group papers – working groups on hold
- Review ARTP/BTS Respiratory Function guidelines (1994) – in progress
- Continue to provide support to membership regarding registration options – in progress
- Educational objectives - completed
- Financial objectives - completed

### Communications

*Chris Jones (CJ) presented the Communications Committee report and detailed the current ARTP Publications:*

- ARTP Journals
  - Inspire, Snews, eXhale

- Monthly Newsletters (email)
- ARTP Website
- ARTP Forum
- Social Media
  - Twitter
  - Facebook

CJ gave thanks to the whole Editorial Group, especially Aidan Lavery and Paul Burns (Inspire), Vicky Cooper (SNEWS), Kim Lewis (eXhale) and Geraldine O'Connell-Ramsay for taking on the Regional Groups Co-Ordinator role.

### Website Statistics

Total Number of Visits = 54,159 (~148/day)

Average of 3.77 pages per visit / 2mins 52secs

	Most Popular Page	Most Popular Source	Country of Origin
1	Homepage	Direct	United Kingdom (1)
2	Members login	Search Engine i.e. Google/Bing/Yahoo	United States (3)
3	Spirometry	British Thoracic Society	India (New Entry)
4	Courses	NHS Careers	Ireland (2)
5	Current Spirometry Courses	Intus Healthcare	Australia (6)
6	Spirometry Full Certificate	Stowood Scientific	France (New Entry)
7	ARTP Conference 2014	Twitter	Netherlands (7)

Facebook and twitter accounts were both reported as having increased activity and i ARTP were currently looking for a Social Media Lead to assist in this area.

Targets for 2014 were given as:

### **Future Website Development**

- Further simplify navigation
  - i.e. create and merge current sections into a Training and Development Section
  - Patient's and Professional sections
- E-Commerce for Courses, Conferences and Books
- Spirometry Section
  - centre search via postcode and map
  - Searchable accredited register
- Online membership database

### **National Strategy Day**

*KS outlined the National Strategy Day that was held in Birmingham on 24th October 2014. The meeting was well attended with 71 delegates and 18 manufacturers exhibiting.*

### **ARTP Collaborations**

*KS gave an overview of current ARTP collaborations that included the Respiratory Futures and Barema.*

### **ARTP Liaison**

*KS outlined the current ARTP Liaison activities:*

- British Thoracic Society
  - Summer BTS meeting
  - Lung Physiology SAG

- Education Committee
- Dept of Health
  - MSC Team
  - Respiratory Futures
- Royal College of Physicians
  - IQIPS Programme
  - National COPD audit
  - HSST Programme
- British Lung Foundation
  - Sleep Apnoea Advisory Group
- National School for Healthcare Science
  - Themed Board
- European Respiratory Society
  - Assembly 9 / Group 9.1
  - VAINS
  - ESD
- Respiratory Education UK / Education for Health
  - Spirometry Training
  - National Inhaler Group

### **Financial Report 2013 - 2014**

*Emma Spence (ES), Honorary Treasurer, presented the financial report and explained the income and expenditure for the preceding year.*

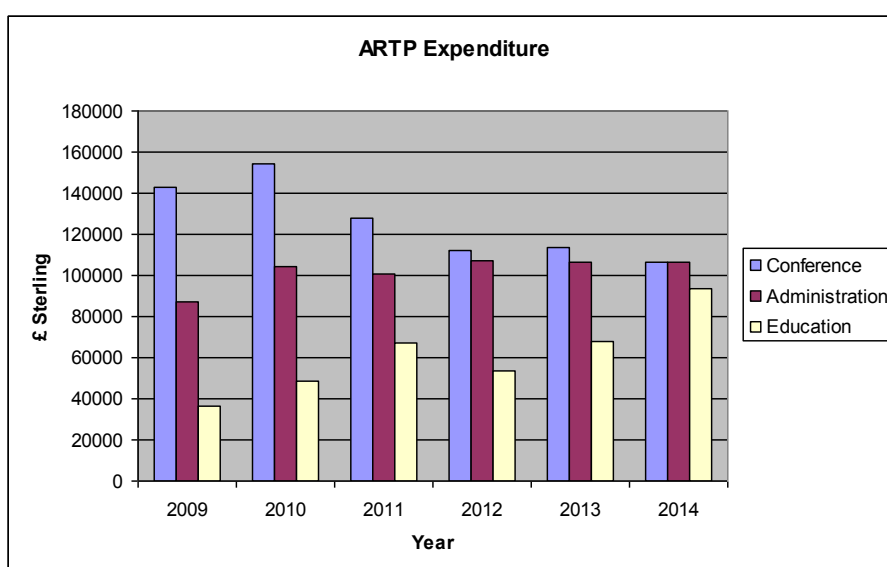
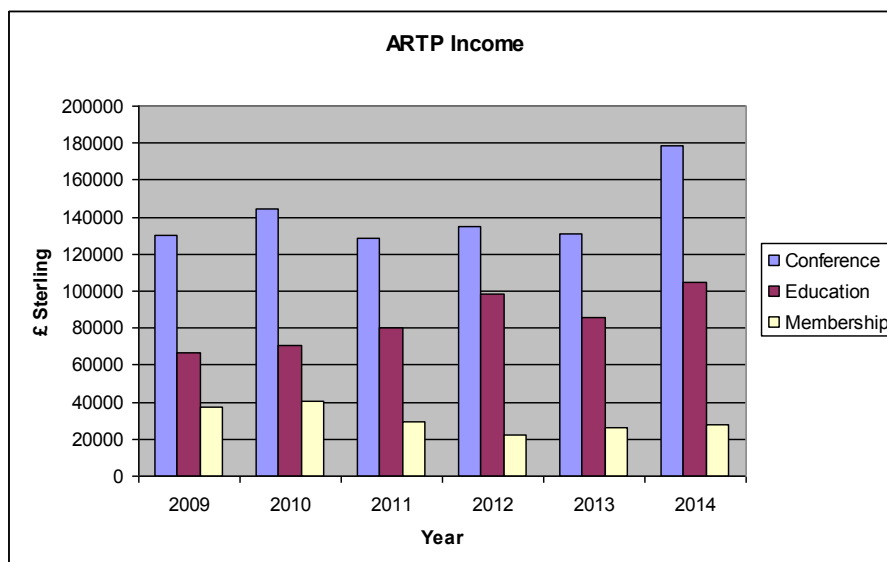
Summary:

**Total assets around £257K**

- 2012/13 - £20K Overspend
- 2013/14 SURPLUS £34,878

All accounts on ARTP website

<http://www.artp.org.uk/en/members-area/accounts/index.cfm>



**The delegates with voting rights accepted the financial report unanimously.**

The financial objectives for 2014 and their progress were reviewed as follows

- Review budget setting for ARTP Committees - completed
- Continue to utilise independent financial advice - completed
- e-merchandising and payments - ongoing
- Business planning process - ongoing

- Review budget setting for ARTP Committees
- Continue to utilise independent financial advice
- e-merchandising and payments
- Business planning process
- Reinvest surplus into ARTP (e-portfolios, website)

ES thanked the following:

- Membership & Manufacturers
- Mark Hubbocks (NED)

*ES gave the following ARTP financial objectives for 2015:*

- EBS Ltd

Please contact: [treasurer@artp.org.uk](mailto:treasurer@artp.org.uk)

ES gave a reminder that members are able to claim tax relief for their subscriptions.

## Education Report

*Joanna Shakespeare (JS), Education Chair detailed the current members of the Education Committee.*

### The following courses ran in 2014:

- Blood Gas Sampling Course X 2
- Physiologist Reporting Course - Bristol
- CPET Course - Glasgow
- Respiratory Muscle - Nottingham
- Masterclass Course – Birmingham
- Paediatric Spirometry – Glasgow & London

An overview of the feedback for these courses was given.

### Courses planned for 2015 were given as:

- Occupational Asthma – Birmingham 24th -25th June
- Blood Gas Sampling – Lichfield March
- Physiologist Reporting Course – Glasgow May
- CPET – Belfast 20-22nd April
- Masterclass Course – Birmingham 20-21st April
- Challenge Testing – London 6th October
- Blood gas sampling and supplemental oxygen - October
- Basic Sleep – Autumn 2015
- NIV – Bristol 19-20th November

JS gave an update on spirometry along with thanks to Jodie Hunt, Vicky Moore, Francesca Turley and all of the Spirometry Committee

- Spirometry Interpretation Course launched at EBS
- Spirometry handbook re written
- New Chair – Vicky Moore
- Launch of new occupational asthma course and spirometry certificate

### ARTP Part 1 Examinations

In 2013/14 there were 2 candidates registered for ARTP Part 1. It was noted that this was the last year for Part 1 examinations

### ARTP Part 2 Examinations

In 2013/14 there were 39 candidates registered for ARTP Part 2

### ARTP Professional Examinations:

#### Exams held in April (6) and October (13) 2014

38 candidates enrolled onto qualification

- Associate – 15 registered, 2 completed
- Practitioner – 23 registered, 10 completed
  - 1 outstanding IRCP
  - 1 failed calculations
  - 5 failures

#### Examination dates were given as:

##### Part 2 Exams

- 21st March
- Resit – 6th June

##### Associate and Practitioner Exams



Spring – 18th April

Autumn – 17th October

The objectives for 2014 were reviewed:

- To support and deliver the examinations for the Practitioner (Level 3) and Associate (Level 1) qualifications - Complete
- Review and launch current Part 1 Handbook to support the PTP programme and the new professional exams – In Progress
- To investigate MSc credits for ARTP professional courses/qualifications – In Progress
- To develop the OSFAs for the STP in association with the NSHCS – Mock stations complete others in preparation
- Launch competency certificate in overnight oximetry – complete

The objectives for 2015 were set as follows:

- Launch Level 2 Clinical Examination
- Support OSFA's for first respiratory cohort
- Launch e-portfolio's for all ARTP competency based qualifications
- Launch revised spirometry and Part 1 Handbooks
- Launch occupational asthma certificate
- Continue to pursue MSc modules
- Host HSST working group

JS gave detailed advice and guidance on the

STP equivalence process.

## ARTP Sleep

*Dr Victoria Cooper (VC) gave details of the membership of ARTP Sleep*

- Respiratory & Sleep 504
- Sleep Only 11

She highlighted that ARTP\_SLEEP committee are in need of more members:

- Paediatric Sleep
- ARNS
- Communications / Secretary
- Membership/recruitment

Ongoing work was detailed:

- ARTP SLEEP Overnight Oximetry Certificate – in pilot stage
- ARTP Basic Sleep Course – details TBC

To be developed:

- ARTP SLEEP Handbook
- SLEEP Modules at all levels (PTP, STP, HSST)

## Constitutional Issues

*KS detailed the current members of the ARTP Council including the Non-Executive Directors who had agreed to stand for a further term.*

<b>President</b>	Dr Brendan Cooper
<b>Chair</b>	Dr Karl Sylvester
<b>Vice Chair</b>	Julie Lloyd
<b>Honorary Secretary</b>	Tracey Fleming
<b>Honorary Treasurer</b>	Emma Spence

<b>Human Resource/ Workforce</b>	Ken Hutchinson
<b>Financial</b>	Mark Hubbocks
<b>Patient</b>	Robin Baldwin
<b>Legal</b>	To be appointed

*He then detailed the ARTP Board format and Committee Chairs and highlighted the addition of a Paediatrics group.*

<b>Communications</b>	Chris Jones
<b>Workforce</b>	Michelle Goodlad
<b>Standards</b>	Ian Cliff
<b>Paediatrics</b>	Kylie Russo/Laurie Smith
<b>Education &amp; Training</b>	Joanna Shakespeare
<b>Events</b>	Alan Moore
<b>Sleep</b>	Dr Victoria Cooper/ Dr Brendan Cooper

*KS asked for members to vote for the following:*

Chair – Karl Sylvester

- Vote to stand for another term

Vice Chair – Julie Lloyd

- Vote to stand for another term

Treasurer – Emma Spence

- Vote to stand for another term

**The membership accepted these nominations unanimously.**

## **ARTP Membership**

### **2015 Key Objectives**

1. Review ARTP/BTS Respiratory Function guidelines (1994)
2. Update policies and procedures and make available on website
3. Expand e-portfolios to deliver e-CPD for members
4. Website investment & development
5. Develop further relationships with external organisations, e.g. ELF
6. Research objectives
7. Educational objectives
8. Financial objectives

### **Benefits of ARTP Membership**

*KS detailed the following benefits of ARTP membership*

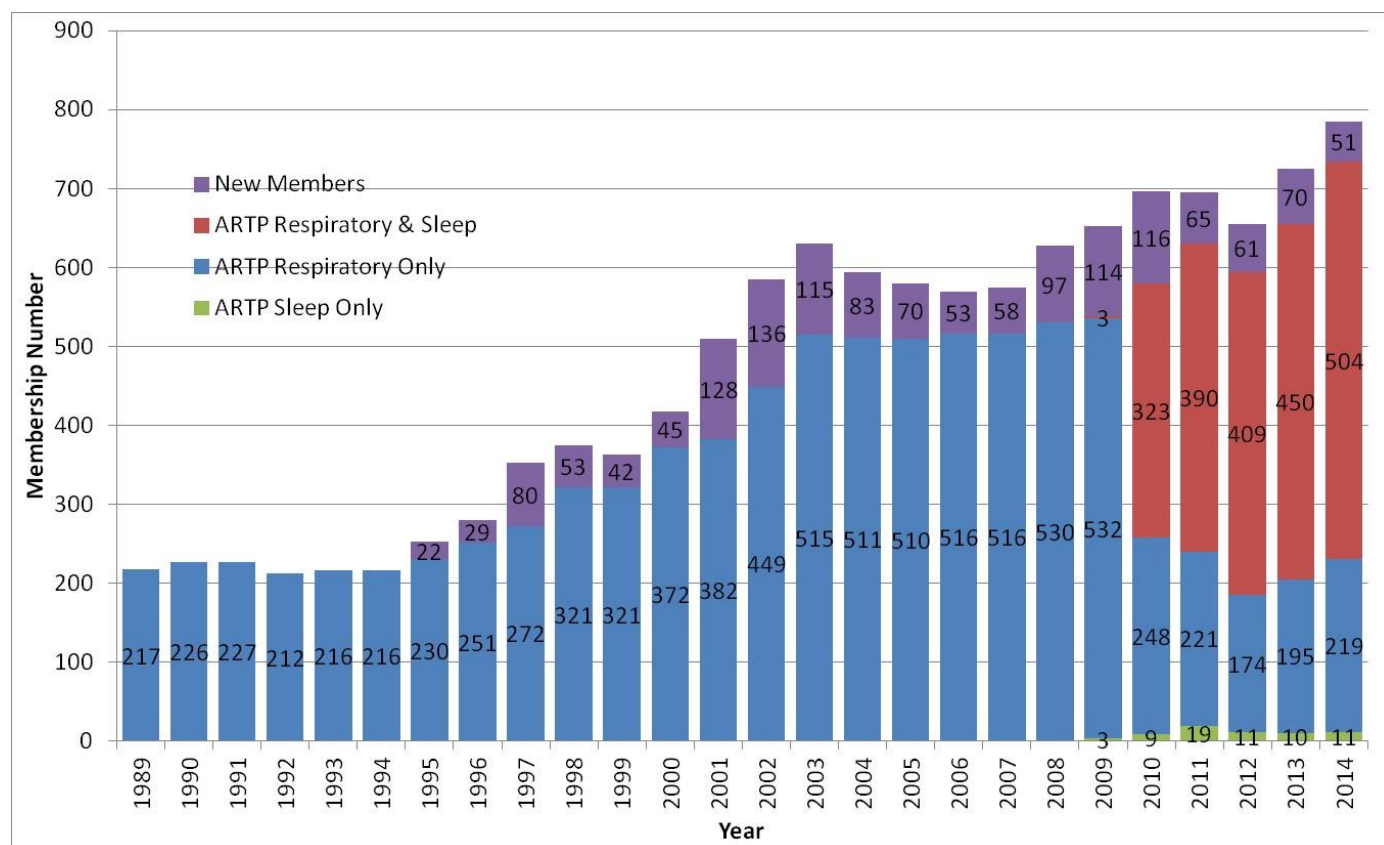
- Discounted Training Course fees
- Subsidised conference attendance
- Grants available (i.e. ARTP)
- Competitive membership fees
- e-Inspire / eXhale / SNews
- Textbooks
- Email Forum
- Website Resources
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*KS then thanked EBS, the ARTP Council, all of the ARTP Committees and working groups for their hard work over the past year.*

*KS asked the delegates if there were any questions.  
As there were none the meeting was brought to a  
close.*

**Tracey Fleming**

**March 2015**



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## POSTER & SPOKEN PRESENTATIONS ARTP ANNUAL CONFERENCE - BLACKPOOL

JANUARY 22nd & 23rd 2015

Over the next 40 or so pages we have published the abstracts that were presented at the Annual Conference this year.

There were 27 **poster** presentations and 4 **oral** presentations accepted for conference.



Clicking on the [abstract number](#) will take you to the required page.

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<a href="#">2</a>	<a href="#">Sarah Burton</a>	The effect of endobronchial valve (EBV) surgery on full pulmonary function results in patients with severe COPD.
<a href="#">3</a>	<a href="#">Laura Wallis</a>	Relationship between alveolar volume and total lung capacity in normal subjects with airflow
<a href="#">4</a>	<a href="#">Kaena Cranstone</a>	PEF/FVC as a marker of interstitial lung disease.
<a href="#">5</a>	<a href="#">Oliver J. Price</a>	The role of impulse oscillometry in detecting airway dysfunction in athletes.
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## POSTER PRESENTATIONS ARTP ANNUAL CONFERENCE 2015, BLACKPOOL

### 1. SPIROMETRY PARAMETER SELECTION METHODS FOR PATIENTS WITH NORMAL AND OBSTRUCTIVE AIRWAYS

*Author: Morgan, CM. Lung Function, Hereford County Hospital, Hereford, England.*

**Aim:** This retrospective audit investigates whether there is significant difference in clinical outcome when using different spirometric parameter selection methods, and discusses which selection method provides the most useful clinical information.

Obstructive airway diseases such as asthma, emphysema and COPD cause narrowing of the airways or weakening of the supportive tissues which hold the airways open, reducing airflow. Spirometry is a vital test in the diagnosis and monitoring of these diseases. Differing methods of selecting spirometric parameters have been discussed and are in use. A difference in reported parameters may change a disease severity category (as defined by NICE 2004) and therefore alter clinical diagnosis and treatment.

**Method:** The Lung Function database was searched for patients aged 20 – 80 who were assessed by spirometry for asthma, emphysema or COPD between 01/01/09 and 31/12/13. Spirometry results – including NICE severity categorisation – were generated from each dataset using the following methods:

'Best Value' = maximum FVC, FEV1 and PEF;

'Best Effort' = maximum FVC; both PEF and FEV1 from the test with the highest PEF;

'Best Test' = all three parameters from

the test with the highest (FVC + FEV1).

In addition, the literature was searched for previous studies on spirometric parameter selection methods and the variables which may affect selection method choice. These studies were critically analysed in terms of providing the most useful clinical information for physicians.

**Results:** 1342 datasets were analysed. Of the datasets, 628 fell within normal range, with 546 demonstrating mild, 249 moderate and 119 severe airway obstruction according to ATS selection methods ('Best Value') and NICE 2004 COPD guidelines.

'Best Value' will always yield the highest possible result for each parameter and was used as a comparison point. 'Best Effort' resulted in an average FEV1 of 0.029L less than 'Best Value' (SD = 0.0381). 'Best Test' resulted in an average FVC of 0.004L less (SD = 0.0137); FEV1 of 0.010L less (SD = 0.0227) and PEF of 0.160L/s less (SD = 0.2247). In all cases, fewer than 5% of patients changed NICE 2004 severity category when a different method was used.

**Conclusions:** The study agrees with data previously published: no significant clinical difference between methods was found. The 'Best Value' method is the standard guideline method and is best used to identify the upper limits of airflow in an individual. 'Best Test' provides an alternative when more detailed selection is not available; it is commonly in use on handheld spirometers. 'Best Effort' may provide more subtle information about dynamic compression of the airways, particularly in patients with severe airway

disease.

Ultimately, the question must be asked: what is the point of spirometry? It has been shown that increased effort of exhalation can lead to increased airflow obstruction. Therefore, effort [PEF] and volume [FEV1] are functionally linked in terms of airway disease. It seems illogical to disconnect the two when reporting, as inferences about dynamic compression and airway collapse cannot be made accurately.

## 2. THE EFFECT OF ENDOBRONCHIAL VALVE (EBV) SURGERY ON FULL PULMONARY FUNCTION RESULTS IN PATIENTS WITH SEVERE COPD.

*Burton SJ Cardiorespiratory Dept, St James University Hospital (SJUH), Leeds, England.*

### Introduction:

This study investigates the physiology of COPD patients and the treatments which are currently available to help them. It explains the mechanics of lung volume reduction surgery, and why it may be necessary to develop new less invasive ways to try and attain the same end goal. Previous studies have shown that endobronchial valve surgery improves FEV1 and exercise capacity, however studies have not focused on the static lung volumes and changes in hyperinflation post valve insertion. Therefore the aim of this study is to focus on all aspects of a full pulmonary function test, in particular the static lung volumes, and assess whether changes can be seen pre and post EBV surgery. Since multiple previous studies (Wan et al., 2006, De Oliveira et al., 2006 and Springmeyer et al., 2009) have found improvements in exercise performance, it would be useful to discover which exact

physiological improvements the EBV treatment causes that are leading to the improvement in exercise performance and could therefore potentially improve quality of life for the patient.

### Methods:

This was a retrospective study looking at pre and post EBV surgery. Full lung function data was collected at SJUH Leeds. A Wilcoxon test was used to determine the significance of results on SPSS software.

### Results:

Results showed no significant improvement ( $p < 0.05$ ) post EBV surgery in any of the parameters measured.

Parameter	Pre EBV	Post EBV	P Value
FEV1	1.57 ± 1.06	1.50 ± 0.90	0.67
FVC	3.36 ± 0.90	3.21 ± 0.66	0.78
FEV1/FVC	44.25 ± 21.19	44.63 ± 20.79	0.67
PEF	273.13 ± 114.52	245.25 ± 77.49	0.16
ERV	1.60 ± 0.70	1.48 ± 0.55	0.48
IC	1.88 ± 0.53	1.98 ± 0.57	0.58
RV	3.44 ± 1.10	3.35 ± 1.22	0.78
TLC	6.96 ± 1.01	6.77 ± 1.20	0.33
RV/TLC	48.88 ± 12.22	48.13 ± 11.84	0.62
FRC	5.03 ± 1.27	4.82 ± 1.50	0.58
DLCO	3.86 ± 1.13	3.60 ± 1.09	0.14
DLCO/VA	0.88 ± 0.36	0.80 ± 0.30	0.06
VA	4.61 ± 0.96	4.60 ± 0.63	1.00

### Conclusions:

It was suggested that the lack of significant improvement post EBV insertion noted during this study could be due to the lack of background knowledge about the patients. This study therefore highlights the importance

of knowing the heterogeneity of disease of patients before offering EBV surgery to them. It suggests a screening process which should possibly be performed to assist targeting those patients who are most likely to benefit from EBV surgery. It also suggests that EBV possibly helps maintain the lung function of patients rather than improve them.

Keywords:

endobronchial valves, emphysema, hyperinflation, atelectasis, collateral ventilation, chronic obstructive pulmonary disease, bulla

References:

De Oliveira HG, Macedo-Neto AV and John AB (2006) Transbronchoscopic pulmonary emphysema treatment: 1 month to 24 month endoscopic follow-up Chest 130 (1) 190-199

Springmeyer SC, Bolliger CT, Waddell TK, Gonzalez X and Wood DE (2009) Treatment of heterogenous emphysema using the spiration IBV valves. Thoracic Surg Clin 19 (2) 247-253

Wan IYP, Toma TP and Geddes DM (2006) Bronchoscopic lung volume reduction for end-stage emphysema :report on the first 98 patients. Chest 129 (3) 518-526

3. RELATIONSHIP BETWEEN ALVEOLAR VOLUME AND TOTAL LUNG CAPACITY IN NORMAL SUBJECTS AND SUBJECTS WITH AIRFLOW OBSTRUCTION

Authors: Wallis, LC 1; Jefferies, R 1. Aneurin Bevan University Health Board and Swansea University1

Inhomogeneous gas mixing, a component of obstructive lung disease, results in increased anatomical deadspace. This may be reflected

by disparity between alveolar volume (VA) and total lung capacity (TLC), thus reducing the VA/TLC%. However, there is limited research evaluating the significance of the VA/TLC%, particularly defining the lower limit of normal (LLN) and the degree to which it corresponds to the forced expiratory volume in one second (FEV1) as a ratio of the vital capacity (VCmax).

Method: Pulmonary function tests of non-restrictive patients performed between 20/4/2012 and 5/12/2013 were allocated to two groups. Group 1 included subjects with FEV1/VCmax>0.7 (n369) and group 2 with FEV1/VCmax<0.7 (n549).

The VA was measured by methane dilution during single breath gas transfer and TLC measured by multi-breath helium dilution. The VA/TLC% was presented as mean ( ) (standard deviation [σ]). Linear regression analysis and Pearson’s correlation coefficient was presented as the correlation coefficient (r), regression equation and the level of significance. Independent t-tests were performed to find significant differences between variables. The LLN for VA/TLC% was given as  $-(1.645 \times \sigma)$  for the sample of normal individuals. A level of significance was set at  $p < 0.05$ .

	VA/TLC% x(σ)	VA/TLC% LLN	Significance	Linear regression analysis
Group 1	89.82 (4.51)	82.40	t(367)=6.55, p=0.00	TLC=0.415+ (1.028*VA)  r=0.975, p=0.00
Group 2	83.73 (7.50)	71.39	t(547)=8.32, p=0.00	TLC=1.029+ (0.978*VA)  R=0.927, p=0.00

Table 1 – summary of results

**Results:**

The mean difference between VA and TLC in group 1 was statistically significant [ $t(367) = 6.55$ ,  $p=0.00$ ] meaning that VA cannot replace TLC even when the estimated anatomical deadspace is included [ $t(367)=4.71$ ,  $p=0.00$ ]. However the correlation is sufficient between VA and TLC ( $r=0.975$ ) to use the regression equation to reliably predict TLC from VA.

The difference between VA and TLC in group 2 was statistically significant ( $t=8.32$ ,  $p=0.00$ ). The VA correlated with TLC ( $r=0.927$ ) giving the regression equation in table 1.

Linear regression analysis identified a significant moderate correlation between VA/TLC and FEV1 percentage of predicted ( $r=0.619$ ,  $p=0.00$ ), FEV1/VCmax ( $r=0.616$ ,  $p=0.00$ ) and RV/TLC ( $r=0.694$ ,  $p=0.00$ ).

**Conclusion:**

The normal value for VA/TLC% is yet to be established; however this study gives a LLN of 82.4%, which corresponds to 82.8% in the study by Roberts, MacRae & Seed (1990) [1]. Whilst the regression equation for group 1 is applicable to a normal population, the regression equation for group 2 cannot encompass the breadth of airflow obstruction severity. To generate accurate regression equations in obstructive patients, given the complexity associated with increasing airflow severity and inhomogeneous gas mixing, further analysis is required.

It was anticipated FEV1/VCmax would be an independent predictor for the VA/TLC% because they are both influenced by airway calibre. However the moderate correlation between these variables suggests their values are not independently analogous.

**Reference:**

1. Roberts CM, MacRae KD, Seed WA (1990). Multi-breath and single breath helium dilution lung volumes as a test of airway obstruction. *European Respiratory Journal*, 3(5), 515-520

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#### **4. PEF/FVC RATIO AS A MARKER OF INTERSTITIAL LUNG DISEASE**

*Authors: Cranstone, K. and Unstead, M.*

*Pulmonary Function Laboratory, Respiratory Medicine, Royal Berkshire Hospital, Reading, UK, RG1 5AN*

Interstitial Lung Disease (ILD) is physiologically characterised by a restrictive ventilatory pattern, impaired gas exchange, maintained airway patency and increased elastic lung recoil pressure. This can often result in accelerated emptying of the lung during forced spirometry. Relationships between Peak Expiratory Flow (PEF) and Forced Expiratory Volume in 1 second (FEV1) have previously been used to assess upper airflow obstruction [1] but little evidence exists investigating the relationship between PEF and volumes in restrictive defects. Therefore the purpose of this study was to investigate PEF/Forced Vital Capacity (FVC) ratio as a marker of ILD.

**Methods:**

Subjects (age:  $71.9 \pm 11.9$  years) with a clinical diagnosis of ILD (FEV1 %pred:  $86.3 \pm 21.2$ , FVC %pred:  $83.9 \pm 23.9$ ), Chronic Obstructive Lung Disease (COPD) (FEV1 %pred:  $49.6 \pm 15.2$ , FVC %pred:  $96.6 \pm 20.3$ ), and individuals with no respiratory disease (FEV1 %pred:  $103.3 \pm 13.7$ , FVC %pred:  $109.7 \pm 11.6$ ). Each subject performed spirometry, single breath TLCO and

static lung volumes via inert gas dilution in accordance with standardised techniques.

PEF/FVC ratios were calculated for all subjects and correlated against markers of restrictive lung disease.

Results:

PEF/FVC ratio was higher in the ILD group (Table 1). PEF/FVC ratio was strongly correlated with TLC %pred (Figure 1) and RV %pred ( $r=-0.76$ ,  $p<0.01$ ) Linear regression analysis was performed for PEF/FVC vs TLC %pred (Figure 1) and PEF/FVC vs RV %pred ( $r^2 = 0.58$ ,  $y=0.018x+4.02$ ,  $p<0.01$ ). No significant correlations were found between PEF/FVC and TLCO or KCO data.

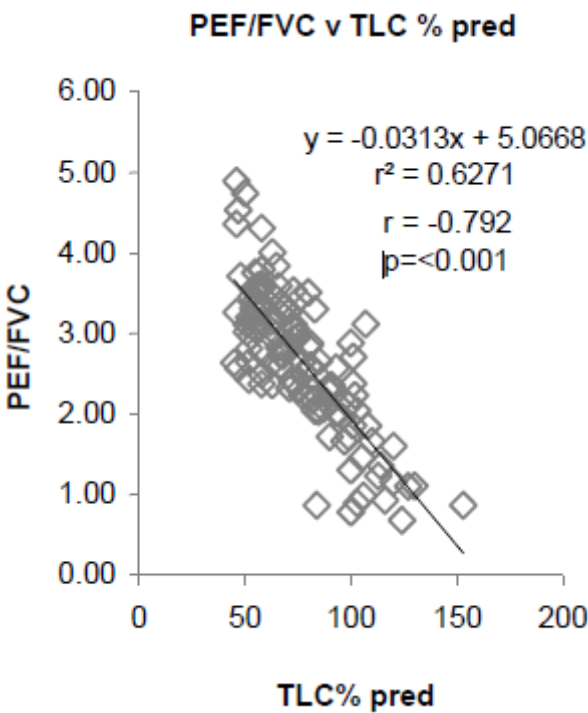


Figure 1

Subjects (n=110)	FEV1/FVC	PEF/FVC	TLC	RV
♀=37 ♂=82	Mean±SD	Mean±SD	% Pred±SD	%Pred±SD
ILD (n=96)	80.0±6.1 †	2.96±0.65†‡	69.4±15.6†‡	59.9±14.8†‡
COPD (n=16)	40.8±11.2*	1.13±0.30b*	111.4±16.6	148.4±34.6*
Normal (n=7)	78.4±3.74	1.96±0.26	101.6±9.7	99.6±7.6

†  $p < 0.01$  ILD vs COPD,‡  $<0.01$  ILD vs Normal, \*  $p < 0.01$  COPD vs Normal. TLCO: Transfer Factor, KCO: Transfer coefficient, RV: Residual Volume, TLC: Total Lung Capacity

Conclusions:

PEF/FVC ratio was significantly higher in the ILD group in the presence of a preserved FVC and can be associated with lower RV and TLC values. This is most likely due to increased lung recoil pressure at TLC and fibrotic lung tissue holding the larger airways open during forced manoeuvres [2]. PEF/FVC values of greater than 3 were associated with significantly impaired RV and TLC. This data supports the hypothesis that PEF/FVC can aid the diagnostic pathway and management for patients with a potential diagnosis of ILD.

References

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2. Woodring, JH, Barrett, PA, Rehm, SR, Nurenberg, P, (1989). Acquired Tracheomegaly in Adults as a Complication of Diffuse Pulmonary Fibrosis. American Journal of Roentgenology, 152 (4), 743-747.

This study has the approval of the Royal Berkshire NHS Foundation Trust (RBFT) Research, Development and Clinical Audit Team.



## 5. THE ROLE OF IMPULSE OSCILLOMETRY IN DETECTING AIRWAY DYSFUNCTION IN ATHLETES

Oliver J. Price<sup>1,3</sup> MRes, Les Ansley<sup>1</sup> PhD, James H. Hull<sup>1,2,3</sup> PhD

1. Faculty of Health and Life Sciences, Northumbria University, Newcastle upon Tyne, United Kingdom (UK).
2. Department of Respiratory Medicine, Royal Brompton Hospital, UK.
3. National Heart and Lung Institute, Imperial College London, London, UK.

**Background:** Impulse oscillometry (IOS) has previously been suggested to provide greater sensitivity than conventional spirometry when employed in conjunction with indirect bronchoprovocation testing for the diagnosis of airway dysfunction in athletes 1-3. However, this recommendation has been based on a highly selected population of symptomatic patients with a high pre-test probability of airway dysfunction. The aim of this study was therefore to compare IOS, spirometry and respiratory symptoms following indirect bronchoprovocation in a screened cohort of athletes.

**Methods:** One hundred and one recreational athletes were recruited for the study. Athletes attended the laboratory on a single occasion. Respiratory symptoms were determined via the Dyspnoea-12 questionnaire. Spirometry and impulse oscillometry (IOS) were performed pre-and post- a eucapnic voluntary hyperpnoea (EVH) challenge. Pulmonary function variables for airway dysfunction positive and negative subjects were compared using a two-way unpaired t-test. The relationship between spirometry and IOS

parameters were assessed using Pearson's product-moment correlation coefficient (normally distributed data) (mean  $\pm$  SD).  $P < 0.05$  was considered statistically significant. The study was approved by the local research ethics committee and all subjects provided written informed consent.

**Results:** Ninety-four athletes completed the study. Sixteen athletes (17%) were positive for airway dysfunction based on spirometry (i.e.  $\geq 10\%$  fall in FEV1) and seventeen athletes (18%) based on IOS (i.e.  $\geq 50\%$  increase in R5) 3. However, only nine athletes (10%) met both diagnostic thresholds. A poor relationship was observed between respiratory symptoms (i.e. Dyspnoea-12 score) and all spirometry and IOS variables. A direct relationship was observed between percentage change in R5 ( $r = 0.65$ ), Z5 ( $r = 0.68$ ), RF ( $r = 0.65$ ), AX ( $r = 0.69$ ) and  $\Delta$ FEV1max ( $P < 0.001$ ). A weak relationship was observed between R20 ( $r = 0.27$ ), X5 ( $r = 0.37$ ) and  $\Delta$ FEV1max ( $P < 0.01$ ).

**Conclusion:** Although IOS and spirometry do not concur precisely; IOS detects additional cases of airway dysfunction in athletes. Impulse oscillometry should therefore be used as an adjunct to spirometry to confirm a diagnosis. Further work is required to establish diagnostic thresholds and fully determine the place of IOS in screening athletes for airway dysfunction.

### References:

1. Evans TM, Rundell KW, Beck KC, Levine AM, Baumann JM. Airway narrowing measured by spirometry and impulse oscillometry following room temperature and cold temperature exercise. CHEST Journal. 2005;128(4):2412-2419.
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AM, Baumann JM. Impulse oscillometry is sensitive to bronchoconstriction after eucapnic voluntary hyperventilation or exercise. *Journal of Asthma*. 2006;43(1):49-55.

3. Rundell KW, Evans TM, Baumann JM, Kertesz MF. Lung function measured by impulse oscillometry and spirometry following eucapnic voluntary hyperventilation. *Canadian respiratory journal*. 2005;12(5):257-263.

## 6. IS THERE A NEED FOR DIRECT ACCESS / IN-SITU FULL LUNG FUNCTION TESTING FOR GENERAL PRACTITIONERS?

*Hughes C. locum physiologist (currently at Bristol Royal Infirmary), Graca A. Maidstone and Tunbridge Wells NHS Trust.*

The study discovers whether there is a need for direct access or in-situ full lung function testing in the surgeries of general practitioners (G.P.'s) in the Maidstone area.

### Methodology

Two methods were used to obtain data.

Firstly, an anonymous qualitative study was sent to 52 G.P.'s surgeries within the Maidstone area of the UK. G.P.'s were asked which diagnostic tools they currently use in diagnosing respiratory diseases, which tests they prefer and which tests they would like to be made accessible to them in the future. Statistical analysis was performed using Excel.

Secondly, a retrospective, case control study assessed the diagnostic accuracy of peak expiratory flow (PEF) alone, spirometry alone, gas transfer and lung volumes testing together

and all of the above tests together. Full lung function tests were anonymised from a hospital database and normality was assessed using Standardised Residuals. Statistical analysis was performed using XLSTAT.

### Results of survey

N = 26. G.P.'s selected multiple options per question. The most commonly chosen options were spirometry and PEF (Table 1)

Table 1. G.P.'s responses when asked which diagnostic tools they currently use in diagnosing respiratory diseases.

Test option	% of G.P.'s currently using this test
Spirometry	100
PEF measurement	96.15
PEF with diary	96.15
Oral steroid trial	84.62
X-ray	80.77
Blood test	80.77
Inhaler trial	73.08
CT Scan	53.85
Other (specified as pulse oximetry)	15.38
Flow volume loop	11.54
Respiratory muscle strength testing	3.85
Lung volume measurement	3.85
6 min walk test	3.85
Skin prick allergy testing	0
Assessment of gas transfer across alveoli	0

Similar percentages were found when G.P.'s selected which tests they prefer to use to aid diagnoses.

In the future, 34.62% of the G.P.'s would like skin prick allergy testing made accessible to them although 34.62% did not answer this question / felt they already had a sufficient

number of test options.

### Results of case control study

N = 209. 539 tests were excluded due to various factors including poor technique. False negative rates were found to be highest for PEF and lowest for all tests together (Table 2).

Table 2. False negative rates found for each

Test	False negative rate	95% Confidence interval for false negative rate
PEF	0.731	0.664-0.797
Spirometry	0.443	0.369-0.518
Gas transfer and lung volumes	0.210	0.149-0.271
All of the above	0.156	0.101-0.210

type of test.

### Conclusion

In the Maidstone area, all G.P.'s use spirometry +/- PEF measurements to aid their diagnoses of respiratory disease. Direct access or in-situ full lung function testing could be a cost-effective way to increase the accuracy of their diagnoses and ensure diseased patients are not missed.

## 7. DIURNAL VARIATION OF LUNG VOLUMES AND RESISTANCES IN HEALTHY SUBJECTS

*Santos, B.<sup>1</sup>; Caseiro, P.<sup>2</sup>; Figueiredo, JP.<sup>3</sup>; Conde, J.<sup>4</sup>*

**Aim:** The human body is composed of many biological functions that vary throughout the day, including lung function. This variability has been documented primarily in subjects with nocturnal asthma, whose lung function worsened during the night, in part as the result of an exaggerated response of a normal pulmonary circadian rhythm (1). Knowing that

lung function variation also occurs in healthy subjects, an investigation into the respiratory circadian rhythm in these individuals is proposed (2). However, the variability may be different from subject to subject, depending on their circadian rhythm and endogenous and exogenous factors, which are related to changes in the size of the airways (3).

Regardless of the limited information about the respiratory diurnal variation, this has become an interesting subject for respiratory medicine in order to improve the diagnostics, conception and therapy in individuals with respiratory diseases (1) (2). Therefore, with this investigation, we aim to detect and describe this variation.

**Methods:** This is an observational and prospective study, of dynamic lung volumes and resistance (IOS) in 50 subjects (25 smokers and 25 non-smokers). A sociodemographic, clinic and life style assessment were carried out, ensuring that all individuals were healthy. Each participant undertook 3 respiratory assessments at 3 different times of the day. Statistical analysis was made using SPSS Statistics software. A percentage medium variation between successive measurements for each parameter was also estimated, which was clinically relevant for values equal to or above 5%.

**Results:** The results show a distinct pattern of pulmonary function diurnal variation in healthy subjects, for most of the assessed lung parameters. FEF25%, FEF50%, IC, ERV, IRV and the resistances were not significantly different in all 3 measurements, while all other parameters changed. The same pattern was described for all demographics. However different variability levels were observed between different groups.

Respiratory Parameter	Mean Variation 1st-2nd Assessment	Mean Variation 2nd-3rd Assessment	Mean Variation 1st-3rd Assessment
FVC	2.62 (SD: 1.82)	2.10 (SD: 1.49)*	2.92 (SD: 2.21)
FEV1	2.52 (SD: 1.92)	1.96 (SD: 1.56)*	3.00 (SD: 2.39)
FEF75-25%	3.20 (SD: 2.12)	2.76 (SD: 2.14)*	3.68 (SD: 2.29)
X5	0.01 (SD: 0.07)	0.02 (SD: 0.06)	0.01 (SD: 0.07)*

Table 1.

Mean variation among three assessments; SD – Standard Deviation; \*statistically significant

**Conclusions:** Some of the results show a respiratory diurnal variation in healthy subjects, similar to previous studies. Therefore, we suggest a further investigation to better understand the diurnal pattern in healthy individuals.

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2. Supervisor Clinical Physiologist
3. Statistical Supervisor
4. President at Coimbra Health School

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## 8. AN UPDATE ON THE UTILISATION OF CARDIO-PULMONARY EXERCISE TESTING (CPET) AT AN ENGLISH ACUTE HOSPITAL

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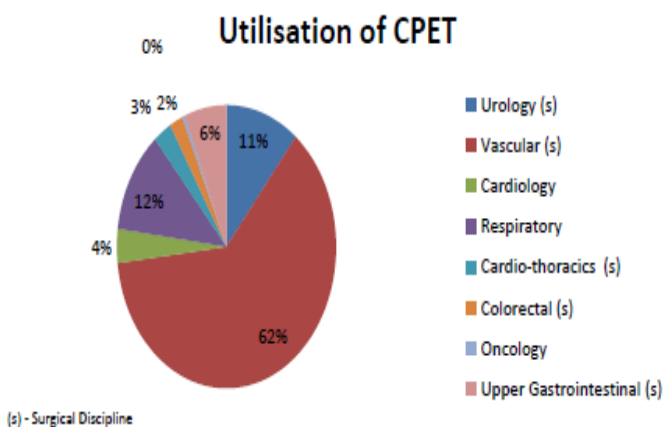
**Background:** CPET has been extensively used in the pre-operative (general anaesthesia) risk stratification. More recently, the utility of CPET has become more defined in the evaluation of unexplained dyspnoea offering a unique assessment tool for these patients and in prognosticating pulmonary hypertension in a rational manner which is also less invasive for patients. [Thing JER, Mukherjee B, Murphy K et al. Thorax 2011; 66 (4): A144]. We set out to evaluate the utilisation pattern of CPET within a 709-bedded central England acute hospital Trust spread across 3 sites in the second year of the establishment of the service.

**Methods:** The source of referral (and reason) for CPET were retrospectively recorded between 1st July 2013 and 30th September 2014 (14 months) and compared to data collected previously between 1st July 2013 and 30th April 2014 (10 months).

**Results:** The total number of CPET referrals received during the 14 month period was 257 out of which 216 (84%) were from surgical disciplines and 41 (16%) from medical disciplines. Vascular surgery submitted the majority of referrals (160, 62%) followed by urological surgery (11%) [see figure 1]. Respiratory Medicine was the source of 12% of all referrals and Cardiology the source of 4%. During the 4 month period vascular surgery

submitted the most referrals (52) and respiratory medicine submitted the second largest amount of referrals (10). There has been on average an extra 2 referrals received per a month (5% increase) from vascular surgery and an extra 1 referral per a month (2% increase) from respiratory medicine in the last 4 months compared to 10 months.

**Conclusions:** The dominant utilisation of CPET by vascular surgery is sustained and expected, given the NHS evidence adoption centre and National Institute for Health and Care Excellence (NICE) 2009 recommendations on risk-stratification for Abdominal Aortic Aneurysm surgery mortality. It seems that the service may still be underutilised despite active promotion. More work needs to be done among the UK general respiratory and cardiology/heart failure communities to promote the awareness, understanding and utilisation of CPET.



## 9. DEVELOPMENT AND VALIDATION OF A FRAMEWORK FOR QUALITY AND SAFETY INDICATORS (QASI) IN RESPIRATORY PHYSIOLOGY

Correia, J.P.F.

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### Background

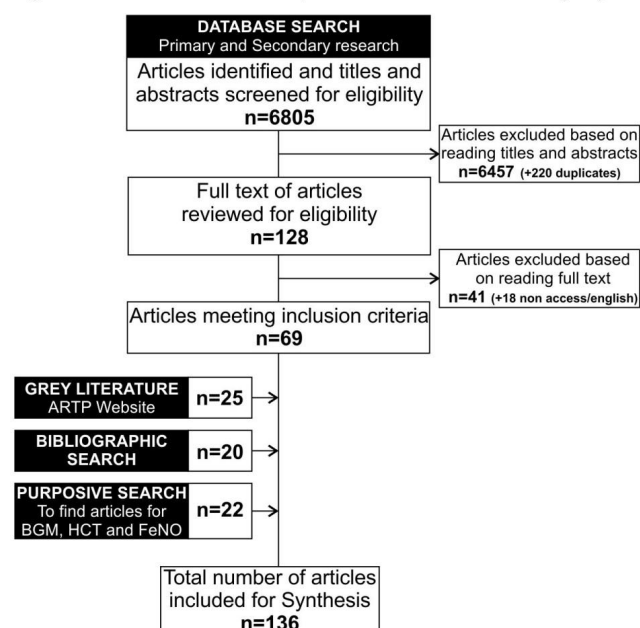
The ever growing complexity of Respiratory Physiology departments and expanding roles of physiologists<sup>1</sup> is likely to contribute to increasing degrees of variation in practice. The context in which this may occur (within or between laboratories) has different repercussions. Nevertheless, there is an overall agreement that it can lead to inaccurate test results and unsafe practice<sup>2</sup>. The purpose of this study is to develop and validate a framework to promote best practice and support Respiratory Physiologists in the daily running of a Respiratory Laboratory.

### Methods

A mixed methods design, integrating a systematic review and an online survey study, was used. The different items and themes that emerged from the review were used to construct the skeleton of the framework. To validate the items an online survey was sent to the ARTP membership.

Searches were performed on the MEDLINE® database (1946 to 30/03/2014) and the ARTP website. A bibliographic search was conducted in secondary research articles. The investigations included in the review were selected based on the findings of the latest ARTP survey<sup>3</sup>.

Figure 1 - Flow chart of search and sequence of determination of article eligibility



Quality wise, the data extracted from the articles relates to interventions and practices that successfully contribute to minimise sources of variation during testing. In regards to safety, barriers and defences to control and manage risk were the topics of interest. The aggregative nature of the review attempts to actively identify points of commonality between the different investigations. A singular framework may be a valid tool if this is well supported by the findings.

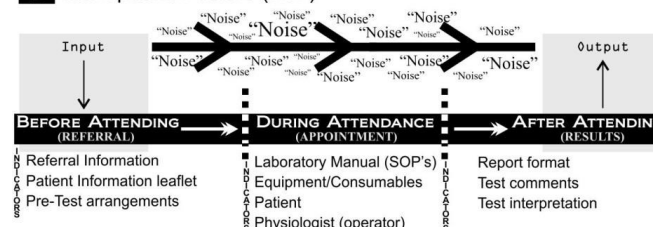
## Results

The information recorded suggests that the items fall under 2 categories. Non-test specific factors (NTSF) and Test Specific factors (TSF). The survey recorded a good agreement for most of the indicators under the 2 categories.

### A Non-Test Specific Factors (NTSF)

A1 - System Resources and Dynamics			
Physical Resources	Leadership	Staffing	Funding
Working relationships	Meetings and briefs	Teamwork	
A2 - Quality Assurance Programme		A3 - Safety and Risk Management	
Equipment servicing	Patient information	Medical emergency routines	Room size and facilities
Training and CPD	SOP's manual	Experience/Training of staff	
Clinical Audit	Planned maintenance (PPM)	Referral information	Identify contraindications
Calibrations/integrity checks	Worksheets	Cleaning and disinfection	
Internal quality assurance	Learning and feedback	Incident reporting systems	
External quality assurance			

### B Test Specific Factors (TSF)



## Conclusions

Measurement is vital to ensure adequate quality assurance and risk management strategies are in place. The framework provides a solid baseline of external and internal factors that may impair the performance of a Respiratory Lab. The information recorded by the different sections of the framework is different, but complementary, focusing on addressing issues on a "whole systems approach". The real value of this tool will only be determined after its use in clinical practice. Integrating the framework into an online based application to provide feedback to physiologists may be particularly useful.

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3. Butterfield AK, Cooper BG, Bucknall M, Sylvester K. ARTP 2012 Survey of Respiratory & Sleep Services. Association for Respiratory Technology and Physiology (ARTP); 2014



## 10. ASSESSMENT OF THE POTENTIAL UTILITY OF ALVEOLAR VOLUME (VA) AS A SURROGATE FOR TOTAL LUNG CAPACITY (TLC)

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### Intro/Background

Patients with chronic lung diseases such as COPD and ILD have routine lung function testing. These tests include spirometry, diffusing capacity and lung volume measurements, which can be time consuming. Measurement of TLC may detect restriction in patients with pulmonary fibrosis(1) and hyperinflation in patients with COPD. VA may be a suitable surrogate for TLC, however airways disease reduces ventilation which cause limitations.

### Aims/Objectives

To determine whether the measurement of lung volumes is necessary in patients with chronic lung disease, by comparing measurements of VA and TLC in two different disease groups.

### Methods

51 patients with pulmonary fibrosis and 208 with COPD underwent full lung function testing; lung volumes measured by helium dilution and carbon monoxide diffusing

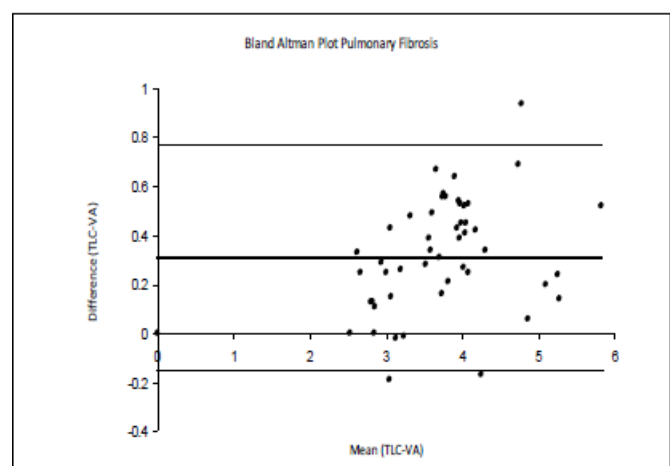
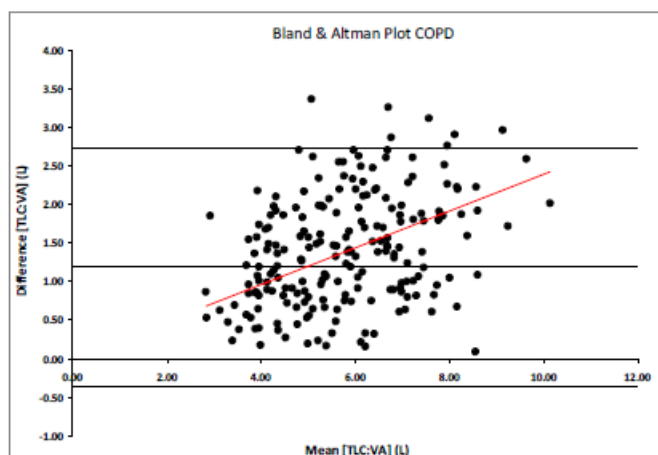
capacity calculated using the Jones Meade single breath method. All tests were performed according to ARTP/BTS Guidelines(2).

VA and TLC were compared using Pearson correlation and Bland Altman analysis.

### Results

Pulmonary fibrosis: VA correlated with TLC ( $r = 0.98$ ,  $p < 0.0001$ ). There was no difference between TLC and VA (mean = 0.31L SE +/- 0.03  $p = 0.99$ ) and did not correlate with FEV1% predicted ( $r = 0.0532$ ,  $p = 0.714$ ).

COPD: VA correlated with TLC ( $r = 0.90$ ,  $p < 0.0001$ ) but the difference (mean = 1.40L SE +/- 0.149) was significant ( $p = 0.015$ ) and correlated with FEV1% predicted ( $r = -0.51$ ,  $p < 0.0001$ ).



### Conclusion

VA may be a suitable surrogate for TLC in

patients with pulmonary fibrosis but not in COPD as there is a significant difference between the measurements in COPD.

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2. ARTP/BTS Guidelines for the measurement of respiratory function. 1994. *Respiratory Medicine* 88, 165-194

## 11. THE FEASIBILITY OF USING COMMERCIAL MULTIPLE BREATH NITROGEN WASHOUT DEVICES IN SCHOOL-AGED CHILDREN

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On behalf of the London Cystic Fibrosis Collaboration (LCFC)

Multiple breath inert-gas washout (MBW) using sulphur hexafluoride (SF<sub>6</sub>) measured by mass spectrometry (MS), is sensitive to early lung disease in children with Cystic Fibrosis (CF)<sup>1</sup> but is not widely available. To increase the accessibility of MBW, commercial devices have been adapted using nitrogen washout (N<sub>2</sub>-MBW). Our aim was to assess the feasibility of two commercial N<sub>2</sub>-MBW devices as supplied by the manufacturers compared to a custom-built MS system in school-aged children.

## Methods

Patients with CF and controls performed MBW

on three devices; the Exhalyzer®D (ECO MEDICS AG); the EasyOne Pro®LAB (nidd Medizintechnik AG) and the MS system (AMIS 2000, Innovision ApS) on the same test occasion (order randomised). Attempts were made to obtain 3 technically acceptable runs/device (maximum 8 attempts on each).

During testing children watched a DVD and were encouraged to breathe normally. Data were analysed using the 'clinical application' setting for both commercial devices, and customised software for the MS. Quality control was in accordance with the ATS/ERS consensus statement<sup>1</sup> and manufacturers' guidelines.

## Results

14 control (mean[range]age: 15.0[12.5-16.7]yrs) and 18 children with CF (13.5[7.8-17.4]yrs) were assessed. The median(range) number of runs attempted were: MS 3(3-8), Exhalyzer D 4(3-6), EasyOne Pro LAB 4(3-8). Average calibration time was shorter for EasyOne Pro LAB (5min) than either MS (11mins) or Exhalyzer D (12min). Total test duration was similar between devices and dependent on disease severity.

3 acceptable MBW runs were achieved in all children using the MS, 75% with the EasyOne Pro LAB, and 47% on the Exhalyzer®D system (see table). Reasons for failure with Exhalyzer D were usually due to technical/equipment problems, whereas for the EasyOne Pro LAB these were generally associated with marked changes of breathing pattern at commencement of washout, leading to exclusion of one or more runs.

Table: Number (n) of technically satisfactory runs according to MBW device

	MS	EasyOne Pro®	Exhalyzer®
n=3	32	24	15
n=2	0	7	1
n=1	0	0	1
None acceptable	0	0	15

## Discussion

Despite use in an experienced MBW centre, our initial attempts to implement commercial MBW devices according to manufacturers' guidelines resulted in a relatively low success rate in schoolchildren when compared to MS. Subsequent feedback to manufacturers has led to further adaptations which should improve feasibility in future, although this has yet to be assessed in very young children.

1. Robinson et al, Eur Resp J 2013

## 12. MITOCHONDRIAL DYSFUNCTION AND EXERCISE CAPACITY IN PATIENTS WITH COPD

G Haji, C Wiegman, J Hull, P Kemp, I Adcock, F Chung\* and M Polkey\*

\* These authors contributed equally

NIHR Respiratory Biomedical Research Unit, Royal Brompton & Harefield NHS Foundation Trust and Imperial College, UK.

Ethics Approval: 12/L0/0088

## Introduction

A dominant role for mitochondria is the production of ATP. This process is more efficient under aerobic conditions. Mitochondria are also important in the

processes that prevent ageing and oxidative stress. Dysfunctional mitochondria in patients with COPD may contribute to less favourable phenotypes and a reduction in exercise capacity.

## Aim

This novel study aims to assess if mitochondrial dysfunction is present in the airways and skeletal muscle of patients with COPD and importantly ascertain its relationship with exercise capacity and endurance.

## Methods

Ex-smokers matched for smoking history and age were recruited. Endobronchial biopsies and vastus lateralis biopsies were obtained on the same day. Additional phenotypic measurements included an incremental exercise test to exhaustion and a six minute walk test. Mitochondria were isolated from tissue and membrane potential as a recognised marker of function was measured using the carbocyanine dye JC-1.

## Results

	FEV1>80% N=10	FEV1 50-80% N=6
Age (years)	63±2	64±1
PYH	36±5	34±7
FEV1 (%pred)	103±3	71±2*
6MW (m)	644±24	503±27*
VO2 Peak ml/kg/min	25±1	17±1*

There is a difference between mitochondrial function in the airways between the two groups (p=0.0012). Mitochondrial function in the airways correlates with six minute walk

distance ( $r=0.57$ ,  $p=0.027$ ) and peak oxygen uptake during an incremental exercise test to exhaustion ( $r=0.74$ ,  $p=0.0015$ ). No such correlations are noted between exercise capacity and muscle mitochondrial function.

## Conclusion

Mitochondrial dysfunction is present in the airway compartment of ex-smokers with GOLD stage II COPD and there is an association between airway mitochondrial function and exercise ability which has not been demonstrated previously.

## 13. VARIATION IN QUALITY AND SAFETY PRACTICES IN RESPIRATORY PHYSIOLOGY LABORATORIES ACROSS THE UNITED KINGDOM: AN ONLINE SURVEY STUDY

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## Background

Over the years, in a continuous pursuit to better control sources of variability, emphasis has been placed in the standardisation of procedures and routines commonly performed in Respiratory Laboratories. In the United Kingdom (UK), despite efforts to standardise practice, there are still reports that suggest some degree of variation<sup>1</sup>. There is however limited information about quality and safety interventions. The purpose of this study is to determine the degree of variation in quality and safety practices and ascertain whether physiologists receive regular feedback.

## Methods

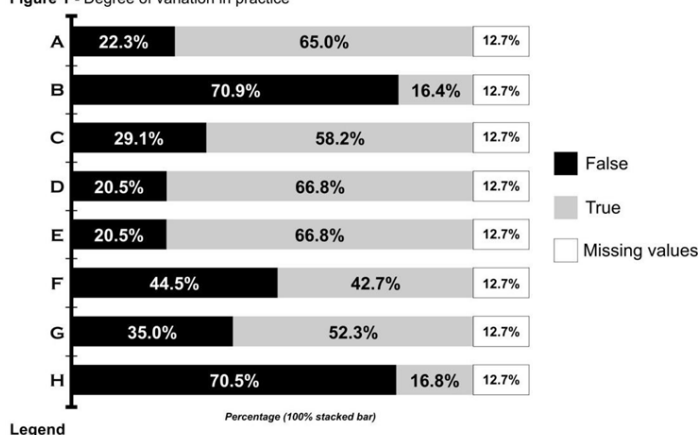
An online survey was sent to the ARTP membership. The quality and safety practices were based on the ARTP Standards of Care and Recommendations in Quality Assurance for Lung Function Laboratories<sup>2</sup>.

## Results

A total of 221 submissions were recorded (25% response rate). The laboratory manual with step-by-step instructions and the inclusion of technical comments in the test report seem to be the most common practices. The majority of respondents also send patient information leaflets to patients prior to their appointment. Interestingly, despite limited reports in the transmission of infectious diseases via the testing equipment, disinfection procedures occur more frequently in comparison to biological quality control, which is known to be a crucial part of a Quality Assurance programme. Lastly, 70.9% of physiologists negate receiving referrals completed in full.

More than 50% of respondents consider their department understaffed. The fact that 46.35%

Figure 1 - Degree of variation in practice



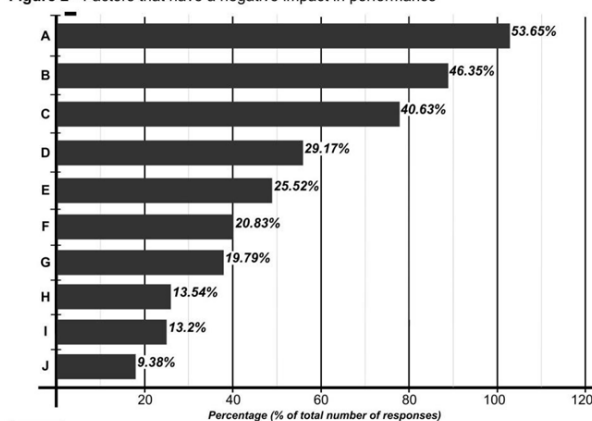
**Legend**  
A - More than half of the workload of this department is to monitor disease progression (F/U patients);  
B - Test referrals are always completed in full with all relevant clinical information (including infection status); C - A patient information leaflet is given to patients prior to their appointment date; D - The Laboratory Manual has a section with step-by-step instructions on how to perform different types of tests; E - It is mandatory to write technical comments (patient cooperation, medication, etc) as part of the test report; F - Laboratory "downtime" is scheduled on clinic lists at regular time intervals to perform BioQC testing; G - Laboratory "downtime" is scheduled on clinic lists at regular time intervals to clean/disinfect the equipment; H - I receive monthly or more regular feedback concerning my work.

of the physiologists report funding restrictions

is likely to explain, to some extent, that short-handed departments are not a result of limited specialised workforce, but due to funding constraints. Another potential explanation is the apparent common poor communication between operational and managerial level. This could either be a result of lack of interest of the latter or deficient escalation of the problem by senior physiologists. A minority of respondents consider not having in their local workplace any factors that may negatively affect performance.

## Conclusions

Figure 2 - Factors that have a negative impact in performance



### Legend

A - Understaffed department; B - Funding restrictions; C - Poor communication between this department and senior level management; D - No administrative support to organize clinics; E - No sense of direction for the development of this service; F - Respiratory/Chest physicians are not interested in the service; G - Very stressful environment; H - None, there aren't any factors that cause a negative impact on the performance of this service; I - There is not teamwork, just a group of individuals with different mind-sets; J - Focus on operational guidelines rather than on patient satisfaction

Variation in Quality and Safety practices exists across the UK. Understaffing, funding restrictions and poor communication between senior management and operational level appear to be the key determinants to suboptimal performance and potentially varying practice. Additionally, only a small fraction of Respiratory Physiologists receive regular feedback. In view of the importance of feedback in the continuous development of physiologists<sup>3</sup>, innovative and pragmatic feedback mechanisms should be established.

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## 14. STATISTICAL ANALYSIS OF PHYSIOLOGICAL QUALITY ASSURANCE DATA OVER FOUR NSPIRE MEASURING DEVICES

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Correspondence: [charliee500@hotmail.co.uk](mailto:charliee500@hotmail.co.uk)

### Aims:

To highlight the importance of regular physiological quality assurance measurements in lung function laboratories

To ensure patient tests are accurate and consistent across measuring devices used in the department

To identify any areas of poor quality

**Background:** Quality assurance (QA) is an essential component of laboratory practice, using both physical (syringe and gas mixtures) and physiological controls. In this study physiological controls were compared between



different devices, and different physiologists.

**Methods:** QA data was obtained for spirometry (FEV1, FVC), lung volumes (body box; TLC, RV) and diffusion (KCO, VA) from four NSpire devices (LT, D1, D2, and D3), and from five physiologists. Data was collected between July 2012 and September 2014. Each of the four measuring devices (2 NSpire HDpft 4000 (involving body plethysmography and fast gas analysers), 2 NSpire HDpft 1000 spirometers (1 connected to a portable laptop) underwent both physical and physiological quality controls at the start of each working week.

Measurements were not always made on the same day for each device.

Each index was statistically compared between devices, within physiologist, using; coefficient of variation (cv), ANOVA (+Tukey's), kurtosis (g2) and skewness (b1) A cv of < 5% is expected. Kurtosis quantifies the shape of the distribution and has an ideal value of 0, with a negative number indicating a flat distribution, and a positive number a peaked distribution. Skewness should be between  $\pm 1$  and reflects the symmetry of distribution.

**Results:** Results for FEV1, TLC and KCO are summarised below. Bold numbers indicate values outside accepted ranges. Data was analysed using GraphPad Prism v6. Similar results were observed for the other physiologists where sufficient data existed to undertake an analysis.

Across measuring devices, D3 has the highest variability in results; with 50% of parameters having a high cv. RV is the most variable unit with every device presenting a high cv.

Statistical differences were found in TLC, VA

and KCO units, see table above.

## Conclusion

These results suggest that regular statistical analysis of quality assurance data may help to ensure more consistent internal quality.

P2: FEV <sub>1</sub>		LT	D1	D2	D3
$\bar{x} \pm SD$		3.36±0.08	3.32±0.13	3.28±0.09	3.33±0.22
cv (%)		2.44	3.96	2.72	<b>6.47</b>
g <sub>2</sub>		0.09	<b>-0.92</b>	<b>-1.20</b>	<b>1.42</b>
b <sub>1</sub>		-0.27	-0.46	-0.28	-0.46
ANOVA	No significant differences between devices				
P2: FVC					
$\bar{x} \pm SD$		4.99±0.11	4.98±0.13	4.94±0.12	4.93±0.14
cv (%)		2.21	2.52	2.42	2.82
g <sub>2</sub>		0.68	0.40	<b>4.45</b>	<b>1.44</b>
b <sub>1</sub>		-0.82	-0.59	<b>1.24</b>	<b>1.20</b>
ANOVA	No significant differences between devices				
P1: TLC					
$\bar{x} \pm SD$			5.22±0.08	5.22±0.06	5.08±0.05
cv (%)			1.61	1.20	0.94
g <sub>2</sub>			-0.002	-1.53	-0.98
b <sub>1</sub>			-0.25	0.0	0.0
ANOVA		D1 & D2 vs D3 p<0.001			
P1: RV					
$\bar{x} \pm SD$			1.47±0.13	1.55±0.23	1.45±0.12
cv (%)			<b>8.82</b>	<b>15.10</b>	<b>8.29</b>
g <sub>2</sub>			0.70	-0.50	-0.46
b <sub>1</sub>			-0.05	0.72	0.42
ANOVA		No significant differences between devices			
P1: VA					
$\bar{x} \pm SD$			5.28±0.14	5.37±0.12	5.21±0.1
cv (%)			2.72	2.19	1.97
g <sub>2</sub>			0.04	-0.01	<b>4.99</b>
b <sub>1</sub>			-0.03	0.42	<b>1.78</b>
ANOVA		D1 vs D2 & D2 vs D3 p<0.001			
P1: K <sub>co</sub>					
$\bar{x} \pm SD$			1.47±0.13	1.55±0.23	1.45±0.12
cv (%)			<b>6.20</b>	4.43	<b>5.24</b>
g <sub>2</sub>			-0.59	<b>-1.12</b>	<b>2.31</b>
b <sub>1</sub>			-0.05	0.72	0.42
ANOVA		D1 & D2 vs D3 p<0.001			

## 15. THE USE OF AGE ADJUSTED D-DIMERS IN THE EXCLUSION OF PULMONARY EMBOLISM

Majid Khan<sup>1</sup>, Jaskaran S Mavi<sup>1</sup>, & P A Brammer<sup>1</sup>

1 The Dudley Group NHS Foundation Trust

### Objective:

Mortality attributed to pulmonary embolism remains a common cause amongst inpatients in the UK, with the Department of Health England approximating in excess of 25, 000 deaths per year, behind cardiovascular heart disease which claims 160,000 lives per year.<sup>1</sup> Consequently the National Health Service have made this a priority issue, thus resulting in the publication guidelines by the National Institute for Health and Clinical Excellence (NICE).

D-Dimer measurement remains integral in the diagnostic criteria for clinically suspected acute pulmonary embolism.<sup>2</sup> D-Dimers when requested inappropriately can often mislead physicians and result in unnecessary investigations, including CTPA.

Righini M et al, alluded to limited clinical worth of D-Dimers in the elderly.<sup>3</sup> Our audit aims to assess the value of a diagnostic algorithm using an age adjusted d-dimer (age multiplied by ten in those over fifty years of age) in those suspected to have a pulmonary embolism.

### Methods:

A retrospective analysis was made of 100 patients who had either CTPA or V/Q scans for suspected pulmonary embolisms in the last six months. Patients were aged over 50 and were included in the audit if there was a low or intermediate Wells score. Those with D-Dimers below 255 (Trust's defined lower limit of

normal) and those with high Wells score were excluded from this audit.

### Results:

A total of 73 CTPA's and 27 V/Q scans were performed. Of these there were 28 positive scans (28%) and 72 negative scans. Of these negative scans, 42 had negative age adjusted d-dimers. Only 2 patients out of the 28 were found to have positive scans but had negative age adjusted D-Dimers.

### Discussion:

Our study shows that the use of age adjusted d-dimers can reduce the number of scans performed for investigation of potential PE with no increase in false negative rates compared to existing D-Dimer thresholds. This could allow better use of limited radiology resources and also avoid the risks of unnecessary radiation and treatment. Subsequently to warrant wider use of age adjusted D-Dimers further studies on much larger scale are required.

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## 16. IS THERE SIGNIFICANT CORRELATION BETWEEN RISK FACTORS OF OBSTRUCTIVE SLEEP APNOEA AND OXYGEN DESATURATION INDEX SCORES?: WITH A VIEW TO IMPROVE REFERRAL SUCCESS

*Author: Mark Hardyman*

Obstructive sleep apnoea (OSA) is ever increasing in the UK. This is thought to be due to the growing prevalence of obesity. However it has been reported that OSA is still under diagnosed and often the issues that can be caused by OSA such as, high blood pressure and diabetes, are treated long before the root cause is discovered. The current study aimed to develop an efficient referral pathway for OSA by identifying the strongest risk factors of OSA and developing regression equations to predict the likelihood a person has OSA.

This study was a two part study, the first part comprised of 100 male and 100 female who had previously undergone overnight oximetry for a query diagnosis of OSA. A number of variables were correlated with their oxygen desaturation index (ODI). Any variables that exhibited a significant correlation were then used to form regression equations. Sensitivity and specificity were then calculated of their effectiveness and predicting OSA in a male group (n=75) and female group (n=37).

Results showed that age ( $r=0.221$ ,  $P=0.027$ ), weight ( $r=0.384$ ,  $P<0.001$ ), BMI ( $r=0.449$ ,  $P<0.001$ ) and neck circumference ( $r=0.444$ ,  $P<0.001$ ) were significant variables for males and weight ( $r=0.274$ ,  $P=0.006$ ), BMI ( $r=0.288$ ,  $P=0.004$ ), neck circumference ( $r=0.322$ ,  $P=0.001$ ) and ESS ( $r=0.251$ ,  $P=0.012$ ) correlated

significantly with ODI in females. Neck circumference provided the highest sensitivity and specificity for both males and females with the male sensitivity and specificity being 97% and 14% and females being 83% and 60%

In conclusion, this study supports evidence that BMI and neck circumference are the strongest predictors of OSA, independent of gender.

## 17. A COMPARISON STUDY OF ONE NIGHT VERSUS TWO NIGHT SLEEP STUDIES IN DIAGNOSING AND TREATING OBSTRUCTIVE SLEEP APNOEA/HYPOPNEA SYNDROME.

*Author: Sola-Ogunniyi, T. Kaaba, A., Wood, C., Fleming, T. Chest Unit, Kings College Hospital*

**Aim:** To determine if there is a clinically significant difference between performing overnight oximetries for one night instead of two

**Background:** Obstructive Sleep Apnoea/Hypopnoea Syndrome (OSAHS) can be screened for using overnight oximetry for one night or two nights. Although two night oximetries are thought to provide more accurate and reliable results, this utilises greater resources compared to one night alone. At the moment, approximately 20 patients are booked in for an overnight oximetry assessment per day at the Chest Unit. This means that assuming all the patients attend their appointment, over than 5000 oximetries will be performed each year. The current waiting time in the department for an overnight oximetry assessment is

approximately 3 weeks. If it is found that performing one night oximetry is adequate, this would:

- Make better availability and use of clinical equipment
- Reduce waiting times for tests
- Speed up study analysis time

We hypothesised that there would be no difference between the first and second nights dip rate or mean SpO<sub>2</sub>.

**Method:** Data was collected retrospectively from October 2012 to July 2013. Patients, who only had one night of data, were inpatients or already established on continuous positive airway pressure (CPAP) therapy were excluded from the study. The dip rate (fall in SpO<sub>2</sub> greater than 4% per hour) and mean SpO<sub>2</sub> from both nights were noted for each patient.

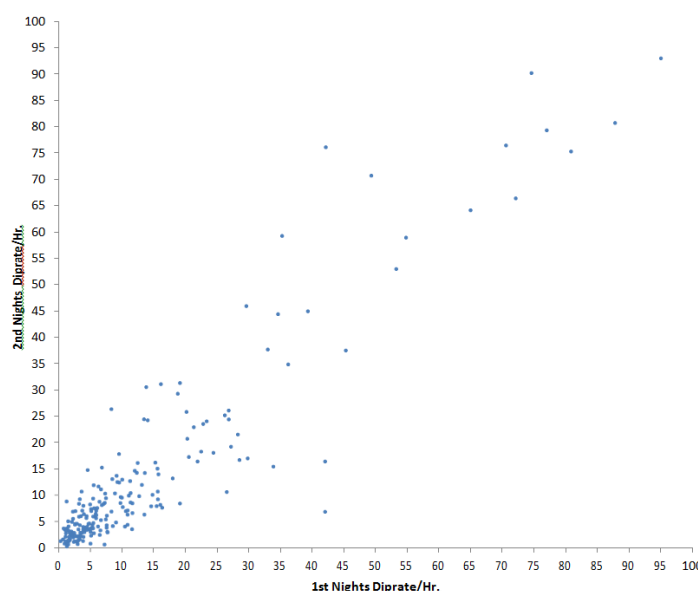
Wilcoxon matched pairs and paired t-test were used to identify any differences between the two groups, where a p value less than 0.05 was considered statistically significant.

**Results:** Data for 183 patients was collected (115 male). There was a strong correlation between the 1st and 2nd night dip rates ( $p < 0.001$ ,  $r = 0.94$ ). The paired t-test showed no significant difference between the dip rates of the two nights ( $p = 0.88$ ). Out of the 183 patients who were reviewed, 56 of them met the criteria for CPAP treatment (dip rate greater than 15/hr) based on either night 1 or night 2. Fifty-two out of the fifty-six patients were correctly identified on the first nights study and were subsequently provided with

CPAP machines. The remaining four patients showed a clinical difference between the first and second night dip rates, where the first night failed to identify moderate sleep disordered breathing that is compatible with CPAP treatment but was detected on the second nights recording. For these patients, the Epworth score ranged from 10 to 14.

Figure 1 Scatter plot showing the correlation between the first and second nights dip rate ( $r = 0.93$ ,  $p < 0.001$ )

**Conclusion:** One night of overnight pulse



oximetry can sufficiently detect sleep disordered breathing. For patients with a mild dip rate and high Epworth sleepiness score a second night recording may be beneficial.

## 18. URGENT SLEEP STUDY REFERRALS IN A PAEDIATRIC LABORATORY - SERVICE EVALUATION

Stonely, NC. Paediatric Respiratory Unit, Noah's Ark Children's Hospital for Wales.



**Introduction:** The Paediatric Respiratory Sleep Service at The Noah's Ark Children's Hospital for Wales provides a Cardio-Respiratory Sleep Study service for South and Mid Wales. Since 2012 the number of sleep Studies performed has increased by 30% and consequently waiting list times have also increased. In January 2013 referrals were re-categorised and the booking system altered with an aim to improve urgent patient waiting times.

**Aim:**

To assess whether re-categorising urgent Cardio-Respiratory Sleep Study referrals has improved waiting times.

To assess why urgent patients are referred and what intervention, if any, is required.

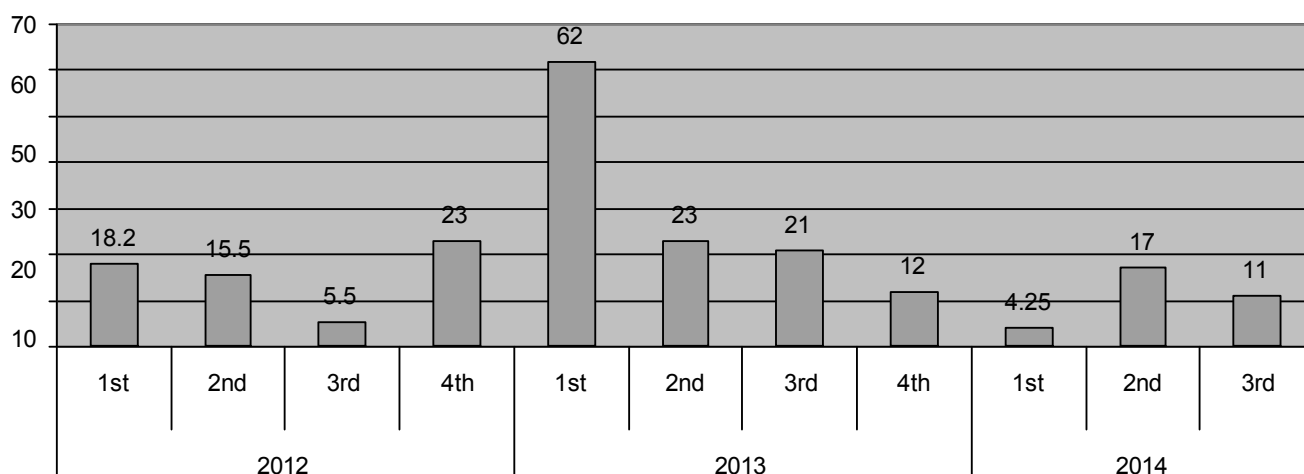
**Methods:** The sleep study waiting list was utilised to investigate the time taken between an urgent referral and the first appointment allocated. A total of 118 urgent referrals were recorded from January 2012 to September 2014. Further appointments allocated due to cancellation by the patient or non-attendances were excluded from this analysis. The reason for the referral and any intervention required were then reviewed to assess whether the classification of urgent patients was appropriate.

**Results:**

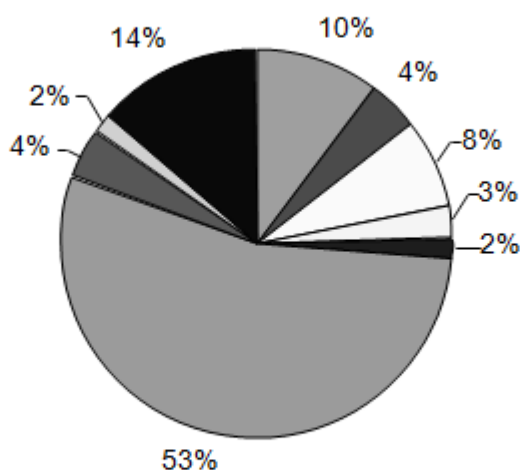
a) Prior to 2013 sleep studies were classed as urgent or routine. Urgent sleep studies were entered onto the "within 1 month" waiting list and then booked into the next available appointment. However, urgent waiting list times peaked in the first quarter of 2013 to an average of 62 days between referral and study date. This was thought to be unacceptable (Figure 1).

Study urgency was therefore re-classified to include three categories: urgent, routine-1-month and routine-3-months. Urgent patients were then appointed as soon as possible into dedicated urgent appointment slots. The number of urgent referrals remained high (29% more urgent referrals in 2013 compared to 2012). Nevertheless, after reclassifying, urgent waiting times dropped significantly, with a mean waiting time of just 11 days between January and September 2014.

### Urgent Referral Waiting



### Reason for Urgent Referral



■ ? Central Breathing Disorder	■ ? Mixed Breathing Disorder	□ Muscle disease - not ventilated
□ Muscle disease - ventilated	■ Obesity ? OSA	■ ? OSA
■ Respiratory	□ Tracheostomy	■ Not specified

b) Referrals are classified as being urgent or routine by the Respiratory Consultants based on clinical history. Since the beginning of 2012, 53% of urgent referrals were for the investigation of possible OSA and 10% for the investigation of a possible central breathing disorder (Figure 2).

Of these urgent referrals, 30% required intervention, 68% required no intervention and 2% required de-escalation of treatment. Interventions included: ENT surgery (60%), NIV or CPAP initiation/adjustment (31%), oxygen therapy initiation (6%) and thoracic surgery (3%).

## Conclusions:

a) Re-categorising the urgency of referrals with the creation of dedicated urgent appointment slots has significantly improved waiting times for urgent patients. This highlights that a degree of redundancy in the booking system is required in order to appoint urgent patients in a timely manner.

b) In this paediatric service the majority of urgent referrals were for the investigation of severe OSA and 30% of urgent referrals required intervention.

## 19. ARE PATIENTS ADMITTED WITH ACUTE PULMONARY EMBOLISM APPROPRIATELY INVESTIGATED AND TREATED?

*Nadarajah CV, Ou Y, Sunnasy R, Wong H, Tsolov A, Simon G.* Basildon University Hospital, Basildon, UK

**Aim** Pulmonary Embolism (PE) is a common acute presentation in hospitals. Until recently the management of PE has mainly been on an inpatient basis. Recent evidence suggests that PE considered to be low-risk can be treated as an outpatient<sup>1,2</sup>. Our aim is to evaluate the current management of PE at Basildon Hospital and to design a protocol to select low-risk patients for ambulatory care.

**Methods** We conducted a retrospective review of case notes of patients referred to Acute Medical Unit with suspected PE from June 2013 to December 2013.

**Results** The average total number of medical admissions per month at Basildon Hospital was 1429. The average number of referrals for query PE was 219 patients over 6 months.

Only 9.1% of patients had Well's score documented. 76.3% had a retrospectively calculated "low-risk" Well's score

Table 1 Investigations conducted	Proportion of 219 patients referred for PE (n=number of patients)	
Well's score documented?	Yes: 9.1% (20)	No: 90.9% (199)
Retrospectively calculated Well's score	>4: 23.7% (52)	≤4: 76.3% (167)
D-dimer done?	Yes: 90.4% (198)	No: 9.6% (21)
Imaging done?	Yes: 93.2% (204)	No: 6.8% (15)

≤4 (n=167). 90.4% had D-Dimers (n=198) done however 15.2% of these D-Dimers were not indicated according to current NICE criteria<sup>3</sup>. These patients already fulfilled >4 points on the Well's score so should have had imaging first-line. 95.1% had CTPA imaging (n=194) but only 44.3% had this on same day (n=86). 18.1% had positive PE (n=37). When PESI score<sup>4</sup> was applied for all patients with PE, 15.2% were excluded based on criteria (n=31) and 52% had low-risk PESI score ≤105 (n=106). Of the 106 patients with low-risk PESI score, 34.9% were ambulated (n=37) when only 2 had a positive PE. The remaining 65.1% (n=69) were hospitalised.

**Conclusions** This audit shows medical staff have not followed current guidelines, requested inappropriate investigations and failed to ambulate low-risk patients. Our calculations predict that low-risk patients can

Table 2 Investigation outcomes	Proportion of 198 patients who had D-dimers		
Appropriate according to NICE criteria?	Yes: 84.8% (168)	No: 15.2% (30)	
Positive D-dimer (>500)?	Yes: 90.9% (180)	No: 9.1% (18)	
Proportion of 204 patients who had imaging			
Mode of imaging and when it was done	CTPA: 194 (95.1%) Same day?: 44.3% (86)	V/Q scan: 10 (4.9%) Same day?: 0%	
Positive PE?	Yes: 18.1% (37)	No: 81.9% (167)	
PESI score done?	Yes: 2.5% (5)	No: 97.5% (199)	
PESI score category?	Excluded patients: 15.2% (31)	≤105: 52.0% (106)	>105: 32.8% (67)

be treated safely as outpatients with a potential saving of £13,660 per month. We have designed a new ambulatory pathway to improve work-up and treatment for suspected PE and will re-audit in 6 months.

## References

1. Safety of outpatient treatment in acute pulmonary embolism. Erkens PM, Gandara E, Wells P et al. *ThrombHaemost*, 2010;8/11(2412-7),1538-7836
2. Outpatient Management of suspected Pulmonary Embolism at a District General Hospital; A 2 Month Review. Benjamin JA, Griffiths A, Power S et al. *Thorax* 2012;67:A123 doi:10.1136/thoraxjnl-2013-204457.305
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## 20. REVIEW OF SURGICAL VS. CONVENTIONAL WEIGHT-LOSS THERAPY FOR TREATMENT OF OBSTRUCTIVE SLEEP APNOEA

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Cardio-Respiratory Department, Pontefract General Infirmary / Leeds Teaching Hospitals Trust, Cardio-Respiratory Department, St James University Hospital*

**Abstract** Current evidence suggests that weight loss as a treatment for Obstructive Sleep Apnoea (OSA) is beneficial and proven to reduce severity; however there is very little evidence as to the most effective modality of weight loss intervention.

**Aim** The aims of this study are to begin correcting this deficit and assess if there is a significant difference in clinical outcome between the two treatment groups and thus adding to the evidence base.

**Methods** This was a retrospective analysis of the patient database of the sleep disordered breathing clinic within the Leeds Teaching Hospital Trust Cardio-Respiratory Department. Ethical approval was attained from De Montfort University and Leeds Teaching Hospitals Trust.

All the patients were under the care of Leeds Teaching Hospitals Trust and had been attending the CPAP (Continuous Positive Airways Pressure) clinic and subsequently discharged as "cured". Patients were only considered for inclusion if they:

- Had more than one overnight pulse oximetry or semi-polysomnography completed
- Had been discharged from the clinic with the reason recorded as “cured”
- Were not receiving any other treatment of OSA i.e. CPAP, Mandibular Advancement Device
- There was specific mention of method of weight loss in the database records.

Patients were divided into two groups; those that had received surgery and those that had lost weight via conventional means. This was done using comments recorded in the database. A comparison between pre and post intervention physiological variables as shown in table 1 was then made. 31 patients (13 surgical and 18 conventional) were retrospectively assessed using SPSS 12: Wilcoxon signed rank test.

### Results.

Characteristic	Surgical	Conventional
Change in Weight (kg)	- 52.58 (34.28)	- 21.9 (19.51)
Change in ESS	- 5.15 (4.85)	- 9.5 (4.53)
Change in AHI	- 33.25 (22.54)	- 28.51(21.51)
Change in BMI	- 18.26 (12)	- 7.54 (6.34)

Table 1: Physiological characteristics of patients post intervention (SD)

Results showed surgical patients lost a greater amount of weight ( $p = 0.001$ ) but there was no significant difference ( $p=0.679$ ) in reduction of Apnoea Hypopnoea index (AHI) score between treatment groups. Conventional

weight loss resulted in a statically greater ( $p=0.001$ ) reduction in Epworth Sleepiness Scale (ESS) then surgical intervention.

**Conclusion** For the treatment of OSA, both interventions result in a significant reduction in AHI regardless of the extent of weight loss. AHI was still  $>5$  event/Hr in the majority of the patients with severity reduced rather than fully resolved. Conventional intervention resulted in a greater reduction in daytime somnolence.

### Key reference

Dixon J, Schachter L, O'Brien P, Jones K, Grima M, Lambert G, Brown W, Bailey M, Naughton M. (2012). Surgical vs Conventional Therapy for weight loss treatment of obstructive sleep apnea. JAMA; Sept; Vol 308, No11 1142- 1149

## 21. VALIDATION OF THE MORPHEUS OX

*Najib, J.A. Stockley, B.G. Cooper.*

Lung Function & Sleep, Queen Elizabeth Hospital Birmingham, B15 2WB

**RATIONALE:** Obstructive Sleep Apnoea (OSA) is a common sleep-related breathing disorder. Overnight screening normally involves simple oximetry monitoring, which may under-diagnose mild sleep apnoea. Elaborate multi- channel devices are capable of measuring respiratory signals in addition to oximetry although they can be difficult to operate and may affect sleep quality. The Morpheus Ox is a new technology that can measure respiratory events via photoplethysmographic signals through a



simple oximeter. If measurements from the two devices are comparable, it may obviate the need for multi-channel studies.

**METHODS:** 26 patients (12 Male : 14 Female, mean age 51) with suspected OSA who had been referred for multi-channel screening (Embletta, SSI, Oxford, UK) were also issued with a Morpheus Ox (WideMed Ltd, Herzliya, Israel) to use conjunctively. Apnoea-Hypopnoea Index (AHI), Oxygen Desaturation Index (ODI), Mean Oxygen Saturation (SpO<sub>2</sub>) and Heart Rate (HR) measurements between the two devices were compared. Mean SpO<sub>2</sub> data were normally distributed and compared with Pearson's correlation and a two-tailed paired t-test. All other data were not normally distributed and compared with Spearman's rank correlation and a two-tailed Mann-Whitney U test.

**RESULTS:** Significant and strong correlations were observed for AHI ( $r^2 = 0.931$ ,  $p < 0.0001$ ), ODI ( $r^2 = 0.950$ ,  $p < 0.0001$ ), Mean SpO<sub>2</sub> ( $r = 0.856$ ,  $p < 0.0001$ ) and HR ( $r^2 = 0.917$ ,  $p < 0.0001$ ). No significant differences were observed in group comparisons for any parameter. Although, on an individual basis, differences were more apparent. In two instances minor differences in AHI and ODI lead to a conflict in diagnosis of "unlikely OSA" vs. "mild OSA".

**CONCLUSIONS:** Generally, the measurement of oximetry and respiratory parameters compared well between the Embletta and Morpheus Ox devices. This is perhaps unsurprising as the two devices were used on the same night. Furthermore, these results are

in agreement with a previous study that compared the Morpheus Ox. to polysomnography [1]. Although there were two instances in the current study where mild OSA was detected through one device but not the other, it would be unlikely to affect the decision to try CPAP when patients are clinically evaluated at consultation. We conclude that the Morpheus Ox is comparable with multi-channel devices for detecting OSA.

**REFERENCES:** 1. Romen A. et al. J Clin Sleep Med 2014; 10: 285 – 290.

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## 22. A REVIEW OF PREDICTORS OF SEVERITY OF OBSTRUCTIVE SLEEP APNOEA

*Butler, A.D & Lloyd, J K. Respiratory & Sleep Investigation Department, Good Hope Hospital, Sutton Coldfield, England*

### Background

Obstructive sleep apnoea (OSA) is estimated to affect up to 4% of middle aged men and 2% of middle aged women (NICE, 2008). Recent OSA awareness campaigns have increased demand on our sleep service by over 25%. This has resulted in longer wait times to diagnose and treat OSA.

It was hypothesised that there may be specific characteristics indicative of OSA severity that would allow us to prioritise patients for assessment and reduce wait times for the most severe patients.

### Methods:

The departmental database (Microsoft Access)

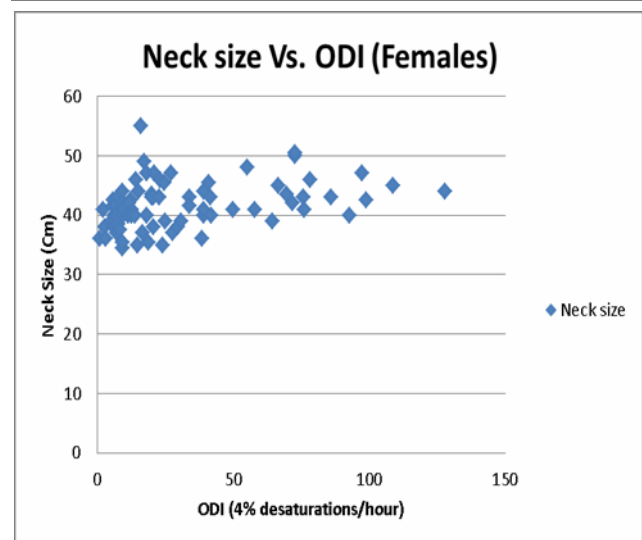
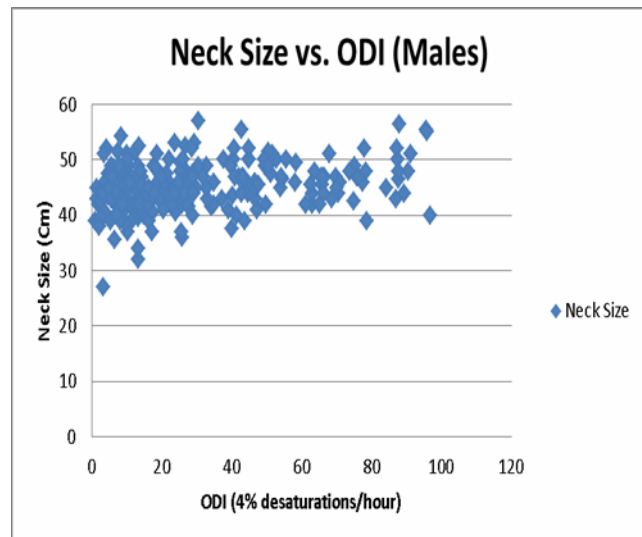
of patients diagnosed with significant OSA (defined as an Oxygen Desaturation Index of  $>15$ , or  $>5-14$  that are highly symptomatic and have not responded to alternative treatment) and treated with Continuous Positive Airways Pressure (CPAP) was reviewed up to end October 2013. An excel spread-sheet was produced of the patients anthropomorphic data, Epworth score and OSA severity at presentation. Additional information including snoring history, smoking history and 12 month compliance with CPAP therapy was also collected and all data was anonymised to ensure patient confidentiality. Patient data was excluded from review if incomplete.

### Results:

Data for 646 patients was analysed, with 462 patients suitable for inclusion. Of the patients included 265 patients had an Oxygen Desaturation Index  $>15$ , and 197 patients had an ODI  $>5-14$  and were highly symptomatic. Of these patients 345 were male and 117 were female.

There was no correlation between Epworth score, smoking history or snoring history and severity of OSA for either sex. Males had a larger neck circumference (45.3cm (range 27-57cm) vs. 41.6cm (range 34.5cm-55cm)) and increasing neck circumference has some correlation with OSA severity.

Average BMI in males with significant OSA (Oxygen Desaturation Index  $> 15$ ) was 35.6kg/m<sup>2</sup>, compared to 40.76kg/m<sup>2</sup> in females.



### Conclusion:

Epworth has no correlation with severity of patient OSA. Female patients have a significantly higher BMI, but a smaller neck circumference before developing significant OSA. Requesting physicians are asked to include BMI on all sleep study requests, and females with BMI  $>40$  kg/m<sup>2</sup> and males with BMI  $>35$  kg/m<sup>2</sup> are fast-tracked for assessment.

### References:

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### 23. INTER-RATER RELIABILITY IN POLYGRAPHY SCORING: QUALITY CONTROL IN A SLEEP SUPPORT SERVICE

Engleman, HM<sup>1</sup>, Mehta N<sup>1</sup>, Thomas MTC<sup>1</sup>, Cooper A<sup>2</sup>, Campbell KHS<sup>1</sup>, Leahy JA<sup>1</sup>, Evans A<sup>1</sup>.

1. Sleep Support Service, Philips Respironics UK, Tangmere, Chichester PO20 2FT
2. Sleep & Ventilation Unit, University Hospital of North Staffordshire, ST4 6QG

#### Aims:

To measure and maintain acceptable inter-rater reliability in scoring of sleep polygraphy studies.

#### Methods:

The Sleep Support Service (previously known as MOST) offers scoring of polygraphy studies to clinical partners, using either partner's 'in-house' or AASM [1] scoring criteria. Since Feb 2013, all internal MOST scorers and an external scorer (AC) score a monthly polygraphy for quality-control (QC) purposes, with scorers' individual apnoea+hypopnoea index (AHI) expected to lie within +/- 15% of the group average AHI.

Each monthly exercise is scored blind of others' results using a) 'in-house' criteria (respiratory events associated with a 4% desaturation) and

b) AASM criteria. QC is promoted and maintained through individual and team training and study review at meetings.

#### Results:

Individual scorers' and the group's mean AHI are seen in Fig 1 (in-house scoring criteria) and Fig 2 (AASM scoring criteria).

The highest inter-rater variability was seen in the first month's exercise. Since then, individual AHI values have been within the 15% tolerance of the group mean except in studies of low severity (group

mean AHI < 10 per hr, e.g. Sept 2013 in Figs 1 and 2), when small differences in absolute AHI yield large percentage differences between scorers.

Comparison of mean AHI values between 'in-house' and AASM criteria show occasionally large differences in severity category, e.g. Jul 2104 in Fig 1 vs Fig 2.

#### Conclusions:

QC has promoted and maintained very acceptable inter-rater reliabilities in polygraphy scoring within Sleep Support Service scorers and against an external scorer. Comparison of two separate scoring criteria systems shows sometimes large differences in outcome of AHI severity.

#### References:

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**Acknowledgments:** Authors thank the staff of

Norfolk and Norwich Sleep Clinic for their partnership.

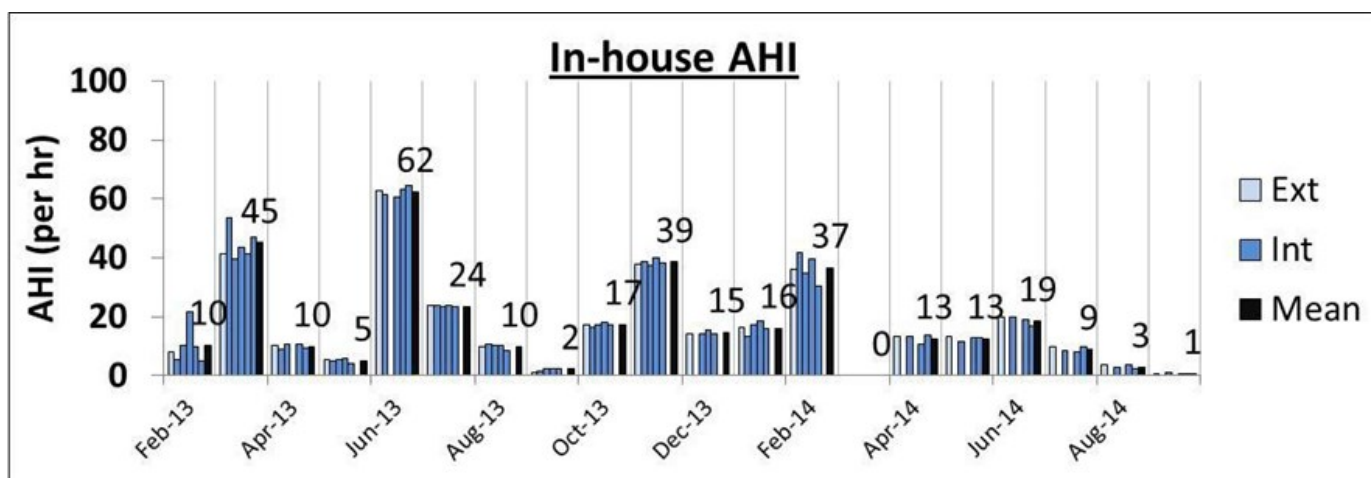


Fig 1: 'In-house' scoring criteria

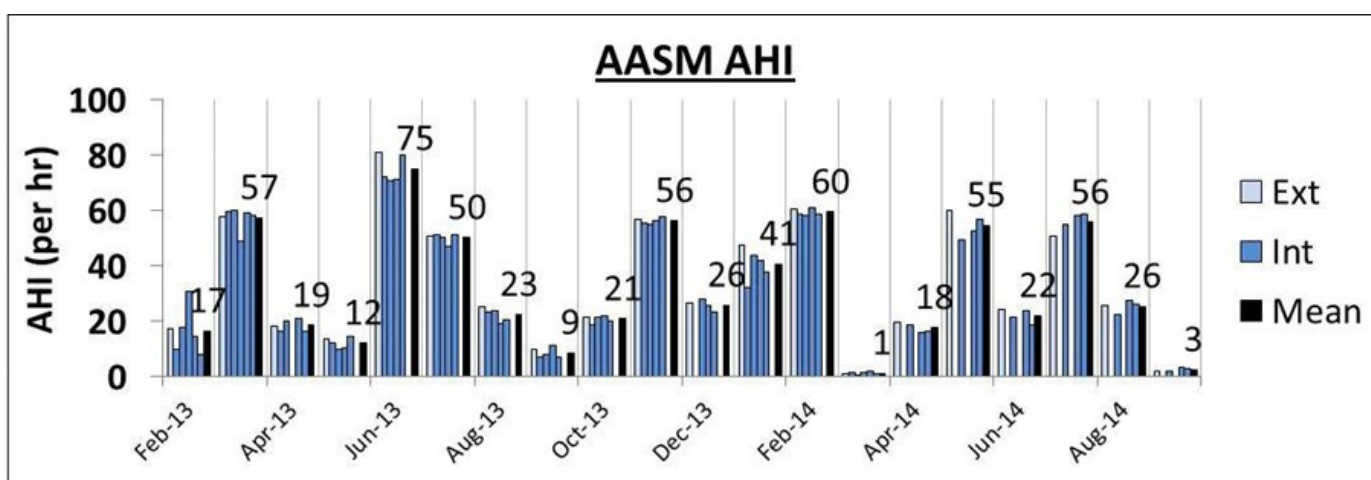


Fig 2: AASM scoring criteria

## 24. OBSTRUCTIVE SLEEP APNOEA: HEALTH ECONOMICS REPORT

Rejon-Parrilla, JC1; Garau, M1; Sussex, J1. Office of Health Economics<sup>1</sup>, London, England. Smith, JC2. British Lung Foundation<sup>2</sup>, London, England.

Based on data in the literature, we estimate that in the United Kingdom (UK) 1.5 million adults have Obstructive Sleep Apnoea (OSA), although only around 330,000 are currently diagnosed and treated. There is an increased risk of road traffic accidents (RTAs) associated with the sleepiness caused by OSA and of

cardiovascular disease and stroke due to the higher blood pressure associated with OSA [1]. The health and economic consequences of treating everyone with moderate to severe OSA in the UK have not been explored in the literature.

**Methods:** We reviewed literature published in peer reviewed journals and in the grey literature about the economics of OSA in the UK and internationally. We identified that Guest et al. (2008) [2] estimated that using continuous positive airway pressure (CPAP) could result in savings to the National Health Service (NHS) and health benefits to patients. We undertook a UK scenario analysis to estimate the health and economic consequences of: Scenario 1) not treating anyone; Scenario 2) treating only a proportion of people with OSA (based on current estimates); and Scenario 3) treating everyone estimated to have moderate to severe OSA in the UK.

**Results:** We estimate that the UK NHS would save a total of £55 million, producing 40,000 quality adjusted life years (QALYs) annually if all people with moderate to severe OSA (45% of the total OSA patient population) were diagnosed and treated with CPAP, relative to none being treated. Relative to the current estimated rate of OSA patients treated across the UK (22% of OSA patients, around 330,000 in total), increasing treatment rates to 45% of OSA patients could yield annual savings of £28 million and 20,000 extra QALYs. If everyone estimated to have moderate to severe OSA in the UK were treated, approximately 40,000 additional RTAs could be prevented each year

relative to the current situation.

### Summary of Significant Results

	Scenario 1) No treatment	Scenario 2) Current estimated uptake	Scenario 3) Increased uptake
Total annual NHS costs (£2012/13)	£604 million	£577 million	£549 million
Total annual QALYs	347,000	367,000	387,000
Total annual NHS cost savings from treatment (£2012/13) (versus no treatment)		£27 million	£55 million
Total additional QALYs gained per annum from treatment (versus no treatment)		20,000	40,000

**Conclusions:** Treating everyone with moderate to severe OSA in the UK could double the cost savings to the NHS and the health benefits to patients. The current provision of services seems insufficient to cover the needs of people with OSA in the UK. Identification of people with OSA needs to be followed by timely cost-effective treatment.

### References:

1. NICE. 2008. CPAP for the treatment of obstructive sleep apnoea/hypopnoea syndrome. NICE Technology Appraisal guidance 139. London.
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## 25. MULTI-CHANNEL ASSESSMENT OF OBSTRUCTIVE SLEEP APNOEA

*J.A. Stockley, B.G. Cooper.*

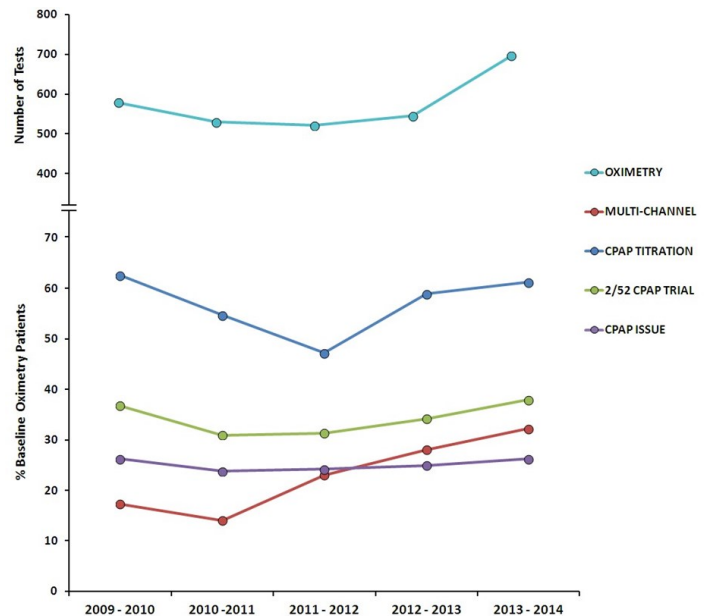
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**Rationale:** A high volume of patients attend our department for obstructive sleep apnoea (OSA) screening by domiciliary oximetry. Subsequent multi-channel screenings are often requested by sleep consultants to confirm the presence or absence of OSA before the decision to try CPAP is made. We sought to determine if the increasing use of multi-channel studies has impacted on the clinical management of our patients.

**Methods:** The number of oximetry studies (Minolta 330i, SSI, Oxford, UK) from September 2009 to September 2014 were recorded. The proportion of these patients that have subsequent multi-channel studies (Embletta, SSI, Oxford, UK), CPAP titrations, two-week CPAP trials and CPAP issues (ResMed, Abingdon, UK) was then calculated. We also compared Oxygen Desaturation Index (ODI) from oximetry and multi-channel by Spearman's correlation and a two-tailed Mann-Whitney U test.

**Results:** Between September 2009 and August 2013, the number of oximetry studies remained constant but increased after September 2013. The proportion of patients that proceed to a multi-channel study has increased from 17% to 32%. Importantly, the proportion of patients who are ultimately issued CPAP has not changed (Figure 1).

Figure 1: Summary of sleep investigations, including number of patients undertaking baseline oximetry and the percentage of these patients that have subsequent investigations



The majority of multi-channel studies (55.6%) were performed on patients with an ODI < 5.0 from baseline oximetry. However, 15.7% of multi-channel patients had a baseline ODI  $\geq 10.0$  and over half of these had a positive Epworth ( $\geq 12$ ). In 68% of cases, multi-channel studies did not influence the decision to try CPAP and, in the remaining 32%, multi-channel results were often disregarded.

ODI was not significantly different between oximetry and multi-channel studies and there was a significant correlation ( $p < 0.0001$ ,  $r^2 = 0.366$ ). Interestingly, oximetry recorded a higher ODI than multi-channel in 43% of cases.

**Conclusions:** While additional data from multi-channel studies may be useful in rare instances, overall their use does not seem to influence the clinical management of our sleep apnoea patients. With the increasing volume of

patients referred to our sleep department and the challenges in adhering to the Response to Treatment Time targets, it would be sensible to review our service as it appears that, in the vast majority of cases, multi-channel studies are unnecessary.

## 26. CENTRAL SLEEP APNOEA (CSA)

### ASSOCIATED WITH OPIOID USE IN A SUBJECT WITH CHARCOT-MARIE-TOOTH DISEASE (CMT) RELATED PERIPHERAL NEUROPATHY

Richard Glover<sup>1</sup>, Julie Lloyd<sup>1</sup>; Good Hope Hospital, Birmingham.

**Introduction:** Chronic opioid use is a risk factor for both central and obstructive sleep apnoea<sup>1, 2</sup>. However, management of chronic pain syndrome is achieved most effectively with opioid therapy.

**Case Description:** A middle aged (59y) male patient presented with symptoms of insomnia, excessive daytime somnolence, and frequent arousals from sleep associated with both pain and sensations of choking. The patient describes daily use of Morphine (110mg/day) to manage chronic pain associated with peripheral neuropathy (CMT).

CSA associated with increased opioid requirements

Limited polysomnography (PSG) (NOX-T3, nox medical) describes an AHI of 48 [CAI: 45.5, OAI: 0.2, HI: 0.8, ODI: 24.5 (4%)]; ASV (ResMed, Autoset CS-A) was commenced. 1 month post therapy demonstrates a significant reduction in daytime tiredness [reduction in ESS from 16, to 8], abolition of insomnia and improvement of sleep fragmentation [consistent (av. 5 hours 30 minutes, 7 nights per week) nightly use of ASV]. A sleep study with ASV therapy demonstrated an AHI index of 4.2 [CAI: 0.0, OAI: 0.2, HI: 3.9, ODI: 3.7 (4%)].

**Discussion:** This case study details a patient with opioid associated CSA, treated successfully with ASV. In this case study, reduction in sleep fragmentation (self-reported, and supported by compliance data)

with reported pain symptoms have further implications: sleep disruption lowers pain threshold<sup>3</sup>; the development of CSA may exacerbate pain sensation through sleep disruption. CSA appears to share a dose-response relationship with opioid use<sup>4</sup>: This chain of events may form a limited negative feedback loop (see figure 1).

**Conclusion:** CSA associated with opioid therapy has high prevalence (30-60% of patient's<sup>1, 2</sup>); effective treatment can be conferred with ASV<sup>5</sup>. Research suggests that individuals treated with opioid therapy and who have EDS and sleep disruption should be screened for SDB. This case study could suggest that control of SDB reduces pain associated arousals from sleep.

Amongst concerns raised by Javaheri et al. (2008), research should aim to identify whether sleep disordered breathing in chronic pain

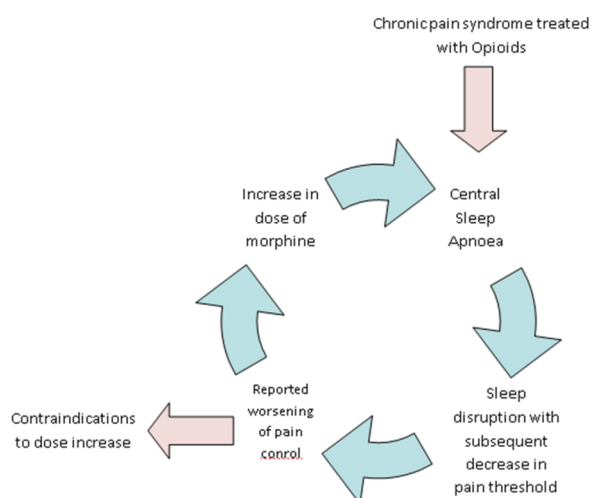


Figure 1. Potential limited feedback loop of

syndrome alters pain control, is associated with increased opioid requirements, and whether effective treatment of SDB improves pain control.

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## 27. VERO VS MINO: DO THE METERS SHOW GOOD AGREEMENT IN THE MEASUREMENT OF EXHALED NITRIC OXIDE?

*Mohammed F Alom, Vicky C Moore*

Birmingham Heartlands Hospital, Heart of England NHS Trust.

**Background:** Fractional exhaled nitric oxide (FENO) is a useful marker for asthma and is a simple and easy test to perform in both primary and secondary care. There are a number of machines available for measuring FENO levels, some of which are portable. Models are often updated, therefore patients may be tested on different machines if they are followed up in clinic, but agreement between these models is not always known.

**Aims:** To compare the Niox Vero and Niox Mino (from Aerocrine AB) portable nitric oxide analysers to ascertain if they have good agreement and to compare different demographic groups which may account for any differences seen between the meters.

**Methods:** Consecutive patients who attended either the asthma or occupational asthma clinic at the Birmingham Chest Clinic, UK, between January 2014 and June 2014 and who performed an FENO measurement as part of their clinical work-up were recruited. Patients were asked to perform a measurement on both the Vero and Mino analysers. Machines were alternated as to which the patient used first. Differences between the meters were compared using the Bland-Altman plot. Patients were divided into different demographic groups so that FENO results could be compared between groups.

**Results:** The Vero and Mino showed significant correlation in their FENO levels ( $p < 0.0001$ ) with differences between the meters ranging from 5-16ppb. The Bland-Altman plot showed the machines had acceptable agreement with 3 outliers outside the 95% confidence limits (Mean of 4ppb, upper limit 11.84ppb and lower limit - 3.84ppb). Males had a larger difference in FENO between the machines than females ( $p = 0.015$ ). Absolute FENO levels were significantly different on both the Vero and Mino between current smokers, ex-smokers and non-smokers ( $p = 0.015$  for the Vero  $p = 0.036$  for the Mino). There were no differences in absolute FENO levels between males and females, those that were reactive to methacholine and not reactive,

on inhaled corticosteroids (ICS) and not on ICS.

**Conclusion:** The Vero and the Mino have acceptable agreeability and are highly correlated. Although there were differences in FENO between the Vero and Mino, they are unlikely to make a difference clinically.

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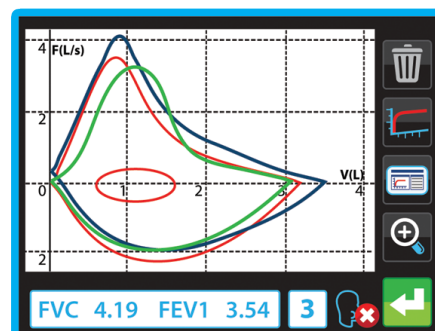
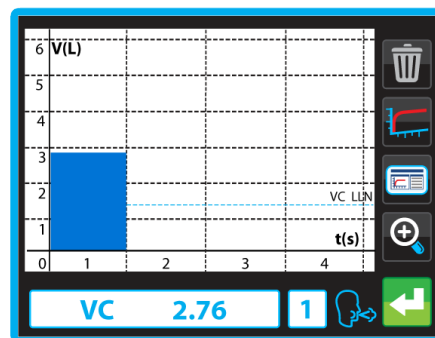
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## ORAL POSTER PRESENTATIONS ARTP ANNUAL CONFERENCE 2015, BLACKPOOL

### ORAL 1. AN EVALUATION OF THE BENEFITS OF A TELEMEDICINE SERVICE FOR CPAP FOLLOW UP

*Fillingham R C, Clinical Measurement Department, Royal Derby Hospital*

#### AIM

The aim of this evaluation was to compare the number of patient visits required to establish patient compliance following initial set up on Continuous Positive Airway Pressure (CPAP) using the Trust's current pathway versus the use of remote tele-monitoring. CPAP trials commenced during the month of September 2013 showed the average number of follow-up visits required in the first year, including the initial set up appointment, was 7.

The information obtained by this audit would determine if the purchase of CPAP devices with remote wireless technology would benefit the department from a cost and time aspect.

#### METHOD

22 patients were set up with CPAP at the request of the referring consultant during June, July and August 2014.

11 patients were given CPAP devices with a wireless module, enabling patients sleep therapy data and prescription settings to be viewed and changed remotely. The remaining 11 patients were not monitored using the wireless module, and followed current practice.

The compliance data of the group of patients using the wireless module were reviewed remotely and a phone call was made to the

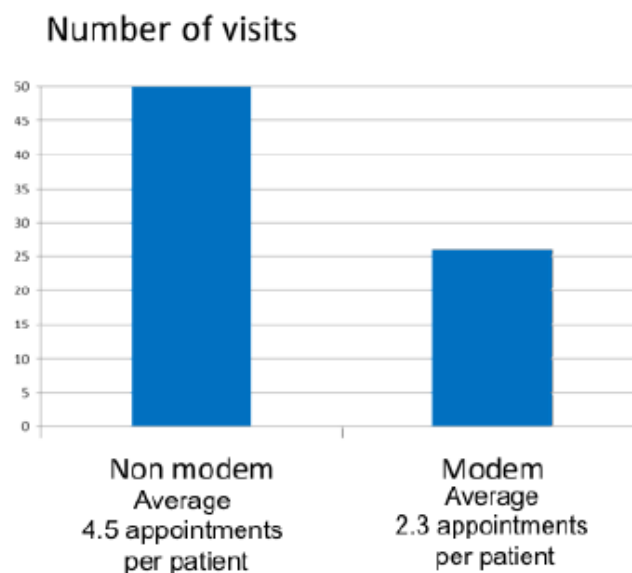
patients within the first week. Adjustments to the pressure were made remotely when required. A further phone call was made if necessary. Once the patient was optimally treated and compliant on their CPAP therapy, they were invited to return for an appointment to remove the wireless module and continue on CPAP unmonitored.

Patients not using the wireless modules followed current practice and were given appointments to return to the department for follow up. Follow up appointments were documented for up to 4 months inclusive of the initial visit.

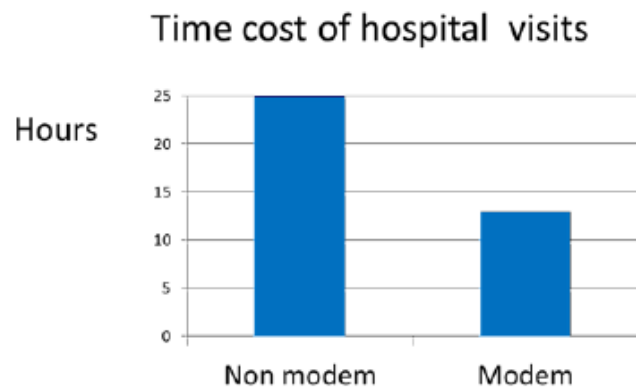
Half an hour was allocated for each follow up appointment. Time allocated for phone calls was based on 10 minutes per call.

#### RESULTS

The 11 Patients who followed the current pathway required a total of 50 appointments, including 7 in which patients did not attend (DNA) (14%). This is an average of 4.5 appointments per patient



Patients who were monitored using the wireless module required a total of 26 appointments, with none of them DNA. This is an average of 2.3 appointments per patient (Figure 1). An average of 1 telephone call per patient was made to the patients with a modem.



## CONCLUSION

This evaluation has shown that significant staff time could be saved from using CPAP devices with remote wireless technology in establishing patient compliance (Figure 2).

The additional 2 patient appointments could be used for seeing more patients and/or used for other service income generation, more than offsetting the increased cost of the device. There may be additional time and resource during their rest of the first year as some of the 2.5 appointments (currently 7) could be saved.

Further study could include looking at why patients return for follow up, for example mask issues, and how best to address these issues. Also, consideration to giving patients humidification as standard with a view to reducing the number of visits for non-

compliance and retrospective issuing of equipment assuming it is cost-effective to do so.

A full version of this abstract can be found in SNews 6:1, pp5-7

## ORAL 2. NEURAL RESPIRATORY DRIVE MEASURED USING PARASTERNAL ELECTROMYOGRAPHY IN CLINICALLY STABLE CYSTIC FIBROSIS PATIENTS: A PHYSIOLOGICAL MARKER OF LUNG DISEASE SEVERITY AND EXERCISE CAPACITY

Smith<sup>1</sup>, C.C. Reilly<sup>2</sup>, V. MacBean<sup>1</sup>, C.J. Jolley<sup>1</sup>, C. Elston<sup>2</sup>, J Moxham<sup>1</sup>, G.F. Rafferty<sup>1</sup> 1 Kings College London, 2 Kings College Hospital

**Introduction:** Assessment of disease severity and progression are important in the management of cystic fibrosis (CF) lung disease. Exercise performance in CF has strong prognostic value, with peak oxygen consumption (VO<sub>2</sub>peak) <32ml/min/kg associated with 60% eight-year mortality rate. Exercise testing is, however, complex and expensive to perform routinely. Measurements of neural respiratory drive, using parasternal intercostal muscle electromyography (EMGpara), reflect the balance of the respiratory system load and respiratory muscle capacity and relates to pulmonary function impairment and exercise-induced breathlessness in advanced CF. We wished therefore, to investigate the relationship between EMGpara, VO<sub>2</sub>peak and distance walked during a field test of exercise performance.

**Methods:** Twenty five patients with clinically

stable CF were recruited. EMGpara was recorded during five minutes of tidal breathing using electrodes positioned in the second intercostal space directly lateral to the sternum. Peak EMGpara per breath was averaged over the final minute of the recording and expressed as a percentage of EMGpara recorded during a maximal inspiratory manoeuvre (EMGpara% max). Spirometry, lung volumes by body plethysmography (n=23) and an incremental shuttle-walking test (ISWT) with breath by breath metabolic data were also performed. Correlations were performed using Spearman's correlation coefficient.

**Results:** Patient characteristics, EMGpara% max, measures of pulmonary function and exercise performance are shown in Table 1. EMGpara% max was significantly associated with residual volume/total lung capacity ratio (RV/TLC  $r=0.692$   $p<0.001$ ), forced expiratory volume in one second % pred. (FEV1  $r=-0.631$   $p<0.001$ ) and thoracic gas volume/total lung capacity ratio (TGV/TLC  $r=0.576$   $p<0.001$ ). EMGpara% max showed the strongest relationship with ISWT distance ( $r=-0.629$   $p<0.001$ ), peak oxygen uptake (VO2peak  $r=-0.672$   $p<0.001$ ) and anaerobic threshold (AT  $r=-0.652$   $p<0.001$ ). Weaker relationships were observed between pulmonary function and ISWT distance (FEV1  $r=0.523$   $p=0.007$ , RV/TLC  $r=-0.455$   $p=0.029$ ), VO2peak (FEV1  $r=0.520$   $p=0.008$ , RV/TLC  $r=-0.496$   $p=0.016$ ) and AT (FEV1  $r=0.497$   $p=0.011$ , RV/TLC  $r=-0.490$   $p=0.018$ ). TGV/TLC showed no significant relationship with ISWT distance, VO2peak or AT. VO2peak was strongly correlated with ISWT distance (0.87,  $p<0.001$ ). Median (Range) EMGpara% max was

significantly higher in patients with VO2peak  $<32$  ml/min/kg (12.5(5.1–34.5)%) compared to patients with a VO2peak  $>32$  ml/min/kg (5.1(3.1–9.8)%) ( $p=0.002$  (Mann-Whitney test)).

	Median	Range
Age	24	16-47
BMI	20.6	18.0-29.4
EMGpara% max	8.1	3.1-34.5
FEV1 (% pred.)	61.3	16.0-101.3
RV/TLC (%)	42.9	22.0-74.0
TGV/TLC (%)	59.5	43.0-79.0
ISWT Distance (m)	630	280-880
VO2peak (ml/min/kg)	24.9	16.8-38.7
AT (ml/min/kg)	15.4	10.3-29.5

Table 1-Patient characteristics, EMGpara% max, measures of pulmonary function and exercise performance in twenty five patients with CF

**Conclusion:** EMGpara correlated strongly with conventional pulmonary function measures in CF and has a closer relationship with exercise capacity than standard pulmonary function parameters. EMGpara% max may therefore represent a promising prognostic marker of CF lung disease progression

### ORAL 3. THE EFFECT OF POSTURE ON VENTILATION USING STRUCTURED LIGHT PLETHYSMOGRAPHY (SLP) IN ALPHA 1 ANTI-TRYPSIN DEFICIENCY (A1ATD).

LC O'Reill<sup>y1</sup>, E Sapey<sup>1,2</sup>, SD Desando<sup>2</sup>, JA Stockley<sup>1</sup>, RA Stockley<sup>1</sup>, BG Cooper<sup>1</sup>.

Lung Function & Sleep Department, Queen Elizabeth Hospital Birmingham 2. University of Birmingham

#### Introduction

Structured Light Plethysmography (SLP) determines changes in ventilatory patterns by utilising relative thorax contribution (RTC), inspiration to expiration ratio (IE50), inspiration time (Ti), inspiration and exhalation flux (Ti/Ttot) & breathing asynchrony by phase angle (PA). [1]

#### Aims

To measure the change in breathing patterns by SLP between sitting and supine in patients with A1ATD with varying levels of respiratory disease.

#### Methods

We measured respiratory signals using Thor3Di (PneumaCare, Cambridge, UK) in 25 healthy controls [11M:14F, mean age 31.3 years (SD +/- 8.9); FEV1: 4.05L (1.05)] and 27 A1ATD patients [16M:11F, mean age 56.0 years (SD +/- 10.4); FEV1L: 2.10 (1.12); FVCL: 4.22 (1.30)] both sitting and supine for 5 minutes and analysed them using Mann-Whitney tests. Ethical approval has been obtained via South Birmingham Ethics Committee.

#### Results

There were differences in both IE50 & Ti/Ttot between A1ATD patients and healthy controls when supine as expected due to the increases in airflow obstruction (See Table1 ).

Parameter	A1ATD (Median)	Controls (Median)	p-value
IE50	1.63 (1.46, 2.09)	1.28 (1.15-1.66)	<b>p=0.011</b>
Ti/Ttot	0.39 (0.36, 0.43)	0.44 (0.39-0.47)	<b>p=0.040</b>

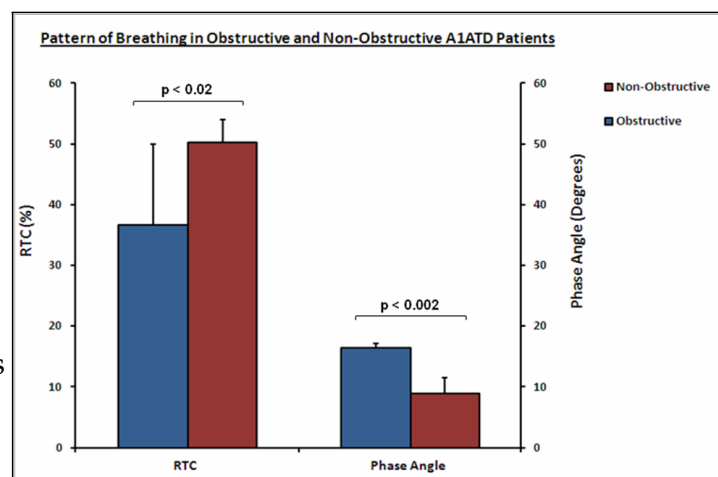
Table 1

There were also significant differences in both RTC and PA in A1ATD cohort suggesting they become more asynchronous from seated to supine. (See Table 2).

Parameter	Seated (Median)	Supine (Median)	p-value
RTC	51 (41, 56)	39 (30-52)	<b>p=0.008</b>
PA	5.7 (5.3, 9.1)	11.3 (6.7-17.2)	<b>p=0.001</b>

Table 2

When supine data from A1ATD patients were separated into those with or without reduced FEV1/FVC ratio (<-1.64SR), the reduction in RTC & increase in PA was greater in the patients with airflow obstruction (Figure 1.)



\*p<0.02; \*\*p<0.002

#### Conclusion

Breathing becomes more abdominally dominant in a supine position, which is

consistent with our current understanding.

Breathing is also more asynchronous in the supine position and this effect is increased in the presence of airflow obstruction.

Further investigations comparing SLP to CT densitometry and spirometry would prove useful in determining whether or not SLP can detect and accurately monitor early pathological changes.

R  
V/  
T

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## ORAL 4. IS THE FRC/TLC RATIO A VALID MEASURE IN CHILDREN WITH OBSTRUCTIVE LUNG DISEASE

*Burns, P D<sup>1</sup> & Sylvester, K P<sup>2</sup>*

1. Respiratory Laboratory, Royal Hospital for Sick Children (Yorkhill), Glasgow
2. Lung Function Unit, Addenbrooke's Hospital, Cambridge

### Introduction:

Hyperinflation is present in some patients with obstructive lung disease in an attempt to reduce early airway closure and augment lung elastic recoil. Presence of static hyperinflation can be determined physiologically. The ERS/

ATS guidelines (1) state that you should use the ratio between residual volume and total lung capacity (RV/TLC %). However, a raised functional residual capacity (FRC) defines the presence of hyperinflated lungs.

We aimed, therefore, to determine whether the FRC/TLC%, in addition to the RV/TLC%, was elevated in children with obstructive lung disease and whether this was greater in those with greater severity of obstructive lung disease.

### Methods:

A retrospective analysis was conducted of data collected over the last 5 years. Children aged 4-18 years were graded into no airway obstruction, mild, moderate and severe obstruction. Normal was defined as an FEV1/FVC% > -1.64 Z scores. ARTP recommendations were used to determine the presence of obstructive lung disease and for severity classification.

Correlations were run on all the parameters against the corresponding FEV1 Z scores. ROC curves were also applied to the data. Sensitivity and specificity measurements were calculated. These were separated into two groups. One with no or just mild airflow obstruction – who were not expected to have hyperinflation and one with moderate and severe airflow obstruction – who would be expected to have hyperinflation.

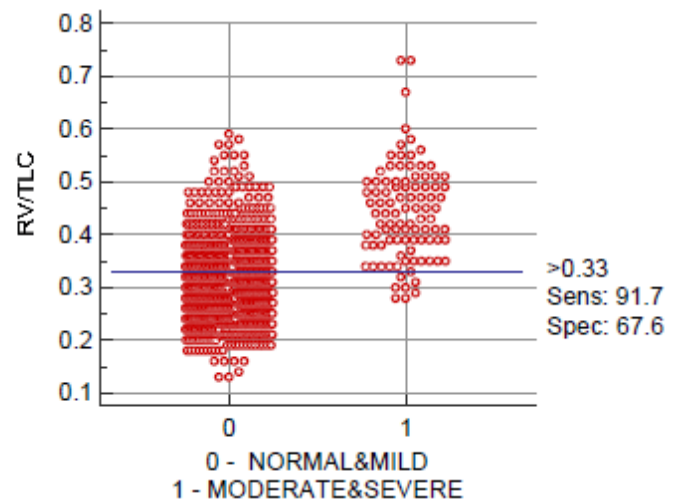
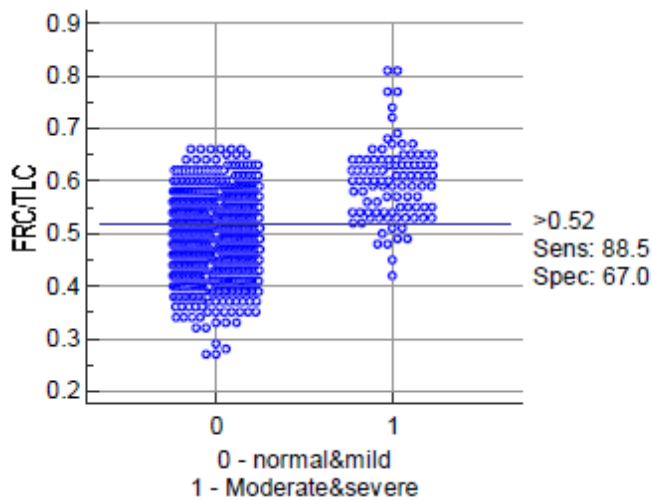
### Results:

3% of children in the normal/mild obstructive group demonstrated abnormal FRC/TLC% versus 38% in the moderate/severe group.



32% of children in the normal/mild obstructive and hyperinflation in this paediatric group demonstrated abnormal FRC/TLC% population. versus 92% in the moderate/severe group.

	FRC/TLC	RV/TLC	FRC Z score	TLC Z score
<b>Correlation with FEV1 Z score</b>	-0.46	-0.6	-0.24	-0.039
<b>Area under ROC Curve (95% CI's)</b>	0.857 (0.834 - 0.878)	0.879 (0.858 - 0.899)	0.809 (0.784 - 0.833)	0.63 (0.60 - 0.660)
<b>Sensitivity (95% CI's)</b>	88.54 (80.4 - 94.1)	91.67 (84.2 - 96.3)	65.62 (55.2 - 75.0)	42.11 (32.0 - 52.7)
<b>Specificity (95% CI's)</b>	66.95 (63.8 - 70.0)	67.59 (64.5 - 70.6)	88.63 (86.4 - 90.6)	83.0 (80.4 - 85.3)



## Conclusions

The FRC/TLC% is elevated in children with obstructive lung disease, with the instance of elevation increasing with increasing severity of obstructive lung disease. RV/TLC% is also increased, but to a greater extent, in children with obstructive lung disease and follows the same pattern with increasing severity of lung disease.

Therefore we postulate that this relationship suggests gas trapping, as defined as an elevated RV/TLC%, is more prevalent at an earlier stage in paediatric obstructive lung disease than hyperinflation, as defined as an increase in FRC/TLC%.

Further research is required to determine the definitive relationship between FRC/TLC%

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