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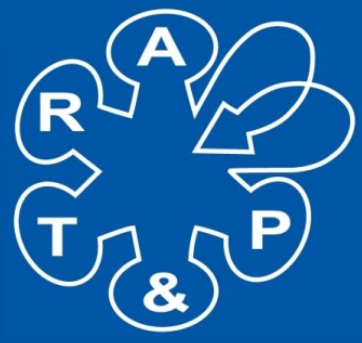

Inspire

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FIRST WORD

1ST AUGUST 2015
VOLUME 16, ISSUE 2

Hello again and I hope you have enjoyed a pleasant summer holiday. Me? I just concentrated on getting this (delayed) issue produced. I am writing this as I read the heartening news that the demise of Helium may have been greatly exaggerated, so don't throw out those TL_{CO} kits yet.

This issue starts with the fantastic news that our President, Dr Brendan Cooper, has been appointed as the first President of the Academy of Healthcare Science. Huge congratulations to Brendan on this appointment. You can read more about it here and in the message from our Chair, which also suggests a tentative foray into the world of e-learning.

The first article proper contains the intriguing line "poor circulation and painted nails", which although resembling a lyric by Morrissey (who he?) is actually from an article on spot-check SpO_2 monitoring.

Following this is an article which questions why we do things the way we do, for example—why do we insist on FRC equilibration of X seconds, why not a shorter period—it would speed things up, wouldn't it? Assuming there was any He left, that is. This is the sort of thing we should be questioning particularly if technological changes improve instrumentation, for example.

Next, well, how would you like to help establish a lung function and sleep laboratory in Iraq? David Jones did so and his fascinating article outlines the difficulties faced in doing so in an atmosphere of political, financial and logistical uncertainty. David's 'Final Remarks' certainly puts many workplace gripes into perspective.

A packed 'On the Blower' follows, with product reviews, a preview of POINT 2015 and an important message re: the encryption of the database system inbuilt into your PFT equipment.

We finish with two articles suggested by topics appearing on the ARTP-forum. The first presents the benefits (and things to consider) if applying to become an ARTP examination centre. The team are keen to attract a variety of centres to improve the variety of choice and equipment to candidates. Give it a read and please email Sandra Davies directly if you are interested.

The second article was suggested by a reader of the ARTP-forum and is the first of what I hope may become a new feature in 'Inspire', where a forum post attracts enough interest to justify an article. The aim of the 'Hot Topic' section is, I think, to provide a light summary of a forum post near to the time of publication.

The first 'Hot Topic' concerns e-cigarettes (or is it 'Vaping-sticks'?) and I was delighted when the author of one post agreed to help produce this.

So that's it—I hope you enjoy the issue. I am grateful to all the contributors and for your suggestions for articles and I encourage you to keep sending them so we can continue to make 'Inspire' a useful advertisement for what the ARTP is all about.

Please contact me at inspire@artp.org.uk if you have any suggestions for articles you would like to see in future issues of 'Inspire'.

Aidan Laverty

A WORD FROM THE CHAIR

Dr. Karl Sylvester

ARTP Honorary Chair

Halfway through the ARTP year, that is halfway between conferences, the summer is here!! Or was that week of sun "it"?

The big news of the year so far, our very own President has been head-hunted and has been appointed as the first President of the Academy for Healthcare Science (see page 6). This is no easy position to take on, trying to keep all Healthcare Scientists, such as life scientists, medical physics, physiological sciences, happy and singing the same tune. Brendan has agreed to stay on as ARTP President until the next conference, which gives us some time in finding a suitable replacement. If you have any suggestions then please let the Board know. I'm sure you'll all join with me in wishing Brendan all the best for his new venture. Although he's supposed to remain impartial I'm sure the soft spot he has for physiological sciences will endure. Brendan still plans to be a relatively active member as a respiratory and sleep professional for ARTP though. I wonder where this ongoing elevation up the ranks will end?!

So as one old war horse leaves the heady heights of ARTP greatness so we welcome others into the fold. Most notably a big welcome to Claire Stacey who has taken on the role of Workforce Chair. Claire will continue the great work this group achieved under the leadership of Michelle Goodlad and already the group is producing excellent work on behalf of the ARTP and its members. We have had a number of requests from home and overseas on how to become a respiratory physiologist, which is great news for our profession, in providing an attractive career. The Workforce group are putting together some standard information to be available on the website in order to answer most of the queries raised.

Our financial position has improved of late and this is thanks to the hard work of our Treasurer Emma Spence and the Finance group, ably assisted by our Financial Non-Executive Director, Mark Hubbocks. Our improved financial position means we are able to re-invest into areas of the ARTP such as the website, education and events plus resurrect some of the bursaries that we had to put on hold.

There are currently aspects of the website which we know could be improved. For example, there is the potential for expansion into areas such as e-commerce. This is not readily (or cheaply) possible within our current contract or provider so we intend on going out to tender to source a better form of e-communication.

Investment in education has meant the introduction of e-portfolios in an attempt to do away with paperwork being shipped around the country. This also makes it easier for students to

demonstrate their competence and easier for examiners to assess this. We're also investigating the possibility of online educational resources, so watch this space.

That just leaves me to wish you all a happy summer. For those of you with kids you'll be pleased to know, unlike the money-grabbing tourist industry, your edition of **Inspire** remains at the same price all year round….FREE!!!

The President's Address

Dr Brendan G Cooper

President, ARTP

Well as summer's go, 2015 has been underwhelming so far, to say the least. Wimbledon was certainly dry, the Ashes has seen two Tests without much rain (although the English fans tears made up for the lack of rain!), but The Open at St Andrews was nearly rained off and average morning temperatures are 2-3 degrees below the annual average.

However, despite the weather, ARTP continues to shine and go from strength to strength with the usual post-conference enthusiasm turning into many meetings, hard graft, much decision-making and planning for the next Conference. Most members aren't aware of the huge efforts that go into all ARTP activities – and all done by ARTP members who have busy work and home lives. It never fails to impress me how hard our professional body works – and generally all for the good of patient care and your ability to deliver that to the highest standards.

I must thank all of you who have sent me kind regards on my appointment as President of the Academy of Healthcare Science. Some of you may have seen the Twitter/Facebook interview sent out by AHCS, but I'd like to address some of the issues here. I reproduce some of the interview here but for the full version see http://www.ahcs.ac.uk/2015/07/an-interview-with-dr-brendan-cooper-president-of-the-academy-for-healthcare-science/

What do you hope to achieve for healthcare science as AHCS President?

My key roles as President are, firstly, to empower all UK healthcare scientists to unite and use our collective voice to influence change for quality scientific service. We should then sell the excellence we have in healthcare science to other medical professions and to awaken the British public to the brilliant resource they have in all of us together.

We, as healthcare scientists have so much more in common with each other than we are different – scientific principles & practice, workforce, training standards, a shared commitment to the quality of scientific services, regulation, values, beliefs and a mutual concern of the future of the NHS and UK healthcare. The one unifying force that we all defend to the hilt is the safety and care of our patients who use scientific services on the clinical pathway.

Why did you apply for the post of AHCS President?

It was a tough decision. I have enjoyed immensely being President of ARTP (Association of Respiratory Technology & Physiology) and planned to continue my full three years of office. However, the AHCS Presidency pulls together many aspects of my career, beliefs and energy to enable me to take my turn as leader of UK healthcare scientists, to work with like-minded scientific leaders and to deliver a vision of AHCS – a vision of UK healthcare science.

There are many opportunities and challenges, but I have enjoyed similar experiences in my career up to now, and I

didn't want to regret avoiding a very unique opportunity. I'm going to give this my best shot, but for this to succeed I will need the support and hard work of many other healthcare scientists across the profession. I am confident ARTP will continue to be a strong force to be reckoned with without me at the helm.

Where do you see healthcare scientists and the profession heading in the future?

Currently there are several different levels of credibility, responsibility and career structure across the different professions. I believe that there will be a more consistent career pathway for all 50 specialties producing a greater respect and understanding of HCS from the medical professions.

How did you get involved in working with professional bodies?

I started in ARTP by establishing myself as "Manufacturer's Liaison Officer" where we built a strong connection with medical device companies and had a healthy "Watchdog" ensuring ARTP members were given a good deal. However, a certain Dr Sue Hill (as she was then), was getting more involved with the Department of Health (DH) and needed to handover the ARTP Chair to "new blood". At an ARTP dinner near Newark, the Executive Committee collectively all pointed the finger, that I should be the next Chair! I really got a taste for the work there and stood for three terms of office – 9 years in total! In that time the ARTP really came of age and went from a well-meaning group of enthusiasts to a truly professional body.

How did you get involved with national scientific issues?

Through ARTP I was "volunteered" to work with the DH on a variety of projects including the "Clinical Physiology Group" which spawned the Registration Council for Clinical Physiologists (RCCP). I also was ARTP representative for the Association of Clinical Scientists and a Partner for HCPC. It was here that I met the great and the good of the Life Sciences and Medical Physics & Engineering communities and began to understand the bigger picture of healthcare scientists.

The UK has some amazing talent in healthcare science that the public know too little about, yet we have an international reputation for our research and services. I want to change that.

AHCS and You

The issues raised are highly relevant to ARTP members, since AHCS is representing you to NHSE, UK Government, the CSOs of the four countries and most of the Royal Colleges in medicine. Your say and input as, we have seen on the ARTP Forum recently, is important and influences our decisions.

Already I have met or have scheduled meetings with Presidents of many professional scientific bodies and Royal

Colleges, the Chief Executive of the Royal Society of Biology, the Chief Scientific Officers for England, Scotland and Wales and also a meeting with the Chief Medical Officer, Dame Sally Davies. At every opportunity I will be mentioning ARTP as an example of best practice in patient facing care if I can. I will also feedback advice and make ARTP members aware of changes that will enable them to get more resources for their service.

I hope this information helps ARTP members understand why I have decided to terminate my ARTP Presidency a year early so that I can concentrate on bringing together all healthcare scientists is the same way that ARTP has; to become a united force to be reckoned with. I would ask that you spend a short time checking out the AHCS website and see how much of what is happening is AHCS is supporting not just those people on STP and HSST schemes, but that the "One Voice" work gets all of us heard together, so that government, other organisations and the public understand what we do, why we are important and why we shouldn't be the targets of government pay freezes. I will always look to ARTP to provide continued leadership, intelligent input and solid support of the Academy.

Obviously I will continue professionally to practice respiratory and sleep physiology and I will undoubtedly still support, advice, contribute and be watching ARTP because it is my professional body. Within the physiological sciences, ARTP have always been ground-breaking in terms of our organisation, effectiveness and achievements, but other professions are catching up and it is important for ARTP that we continue to look outwards as well as seeing the bigger picture of healthcare science as whole.

In the meantime until the end of the ARTP 40th Conference in January I will remain ARTP President and will continue to fight for our profile, standards, quality and governance.

Being your ARTP President is the "best job in the world" and I have been privileged to have been elected by you into that role.

Dr Brendan G Cooper

President, ARTP

To find out more about AHCS you can read the 'Vox' newsletter at http://www.ahcs.ac.uk/news/vox-the-ahcs-newsletter/.

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The importance of spot-check arterial oxygen saturation monitoring in patients referred for Pulmonary Function Tests

Earle, C.L., Respiratory Department, Salisbury District Hospital

INTRODUCTION

Spot-check pulse oximetry for estimating arterial oxygen saturation (SpO_2) is a widely used practice in multiple clinical scenarios, one of which is during pulmonary function tests (PFTs). Pulse oximetry spot checks are quick, non-invasive and the test easily gives an indication of a patient's oxygen level, however, the biggest limitation is the accuracy of the measurement.

The manufacturer of the pulse oximeter used in this study (Pulmolink Oxi-Pulse Tabletop Pulse Oximeter, Charing, UK) has a stated accuracy of ±2% in readings from 70-100% however it is known that a number of errors (e.g. poor circulation and painted nails) can also reduce the accuracy of an SpO_2 reading[3] . Clinically, this accuracy means that 68% of the time the SpO_2 result will be within 2% [6].

Although discrepancies in the accuracy of an SpO_2 reading can make clinical decision-making difficult, it is a useful indicator when deciding whether to commence with a long-term oxygen therapy (LTOT) assessment. Long-term oxygen assessment appointments can be time-consuming, due to the nature of the test required. British Thoracic Society (BTS) guidelines suggest that after increasing the flow rate of oxygen to the patient, it is necessary for them to rest for at least 30 minutes before blood gas analysis can be taken [2]. This can easily result in appointments lasting over an hour. It then becomes important for departments to ensure suitability when allocating LTOT appointments to patients.

AIMS

- To evaluate the clinical usefulness of routine SpO_2 spot checks
- To identify potential hypoxic patients and refer for blood gas analysis of oxygen
- To support the use of spot checks and/or blood gas analysis as part of routine lung function appointments

METHODS

A total of 202 patients referred for lung function tests between 14th January 2015 and 22nd April 2015 were recruited to the study. Patients were placed into three groups; *'no data'*, *'SpO_2 ≤93%'* and *'SpO_2 ≥94%'*. All SpO_2 data was recorded at the time of the PFT, normally, in the four-minute rest period between gas transfer manoeuvres.

Patients who fell into the 'SpO_2 ≤93%' group were retrospectively looked up on the hospital Oxygen Database to identify if they were known to the Oxygen Team.

RESULTS

There were 19 (9%) patients with no data. This

group included patients suffering with circulatory problems resulting in potentially erroneous recording of SpO_2. Of the 152 patients left in the study, 31 (20%) had a recorded SpO_2 ≤93% (Figure 1).

Within this 'potentially hypoxic' group of patients, 5 (16%) were already under the care of the Oxygen Team prior to their PFT appointment (Table 1). One patient was referred to the Oxygen Team following their PFT appointment (Table 1). The remaining 25 (81%) potentially hypoxic patients were not known to the Oxygen Team (Figure 2). Due to restricted appointment times, it was not possible to compare the SpO_2 recorded during PFT testing to an arterial or capillary blood gas (ABG/CBG). Only those patients who were within the oxygen service had the opportunity for an ABG/CBG, but even then, not all of these patients had an ABG/CBG performed at rest, without oxygen (Table 1). Interestingly, the patient who was referred to the oxygen service post-PFT's had an SpO_2 recorded 3% higher when they attended Oxygen Clinic (93%) , than at the time of PFT's (90%). The pO_2 recorded from a blood gas was documented as 7.0kPa; confirming the diagnosis of hypoxia.

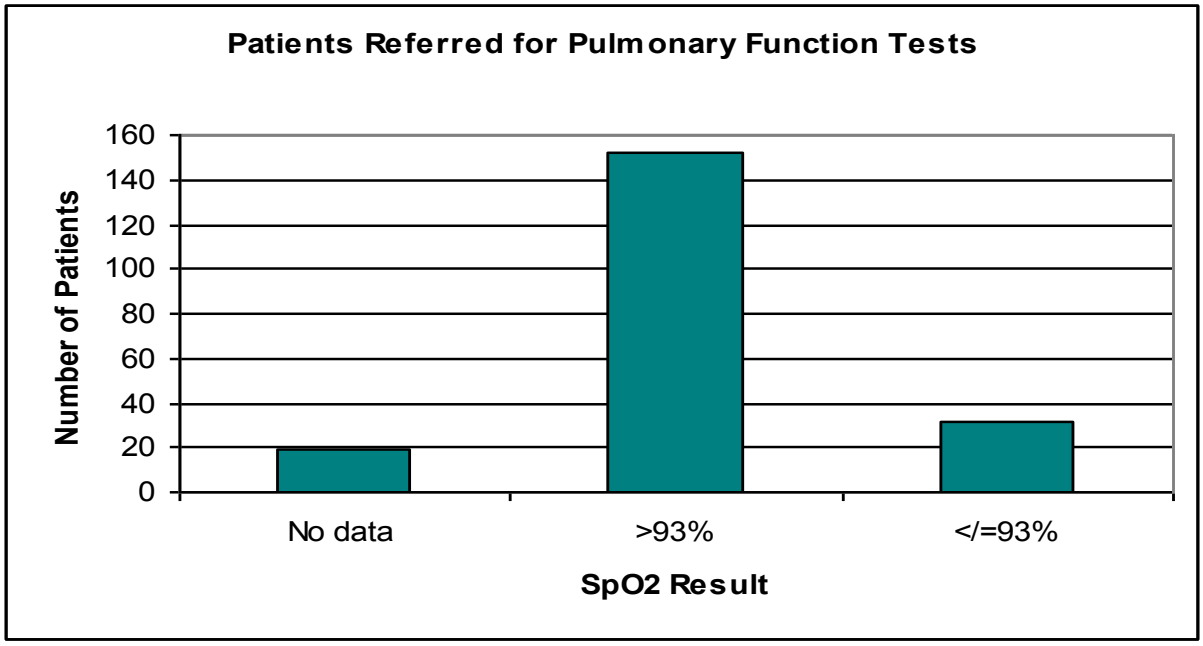

Figure 1 shows the number of patients in each group; no data, SpO_2 ≤93% and SpO_2 ≥94%

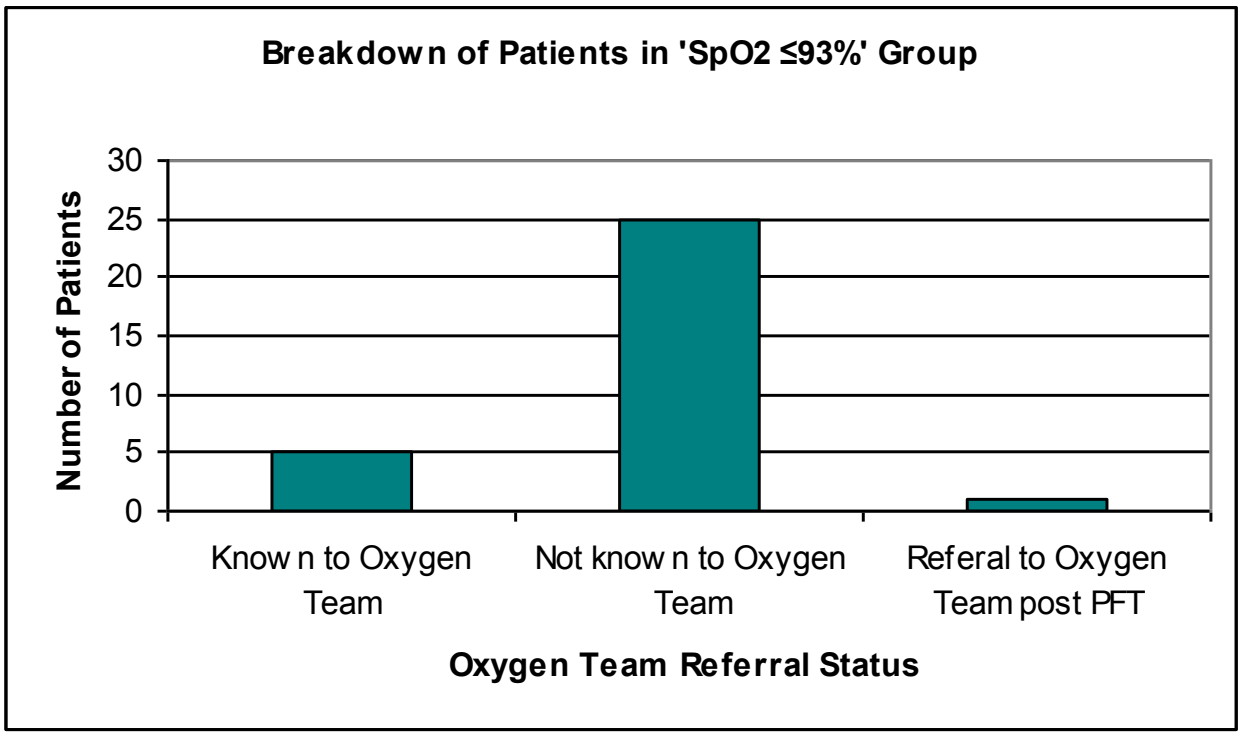

Figure 2 shows the number of patients who are known to the Oxygen Team

i.e. those who have had blood gas analysis to confirm LTOT suitability

Patient Number	pO2 recorded from ABG/CBG	SpO_2 % measured at time of ABG/CBG (or most recent oxygen clinic appointment if no ABG/CBG)	Date ABG/ CBG	SpO_2 Measured at time of PFT
1	8.69 kPa (on 1l/min)	93% (on 1l/min)	19.2.15	86%
2	9.31kPa	95%	17.12.13	88%
3 (referred to Oxygen Clinic post PFT's)	7.00kPa	93%	19.3.15	90%
4	8.62kPa	90%	25.2.15	90%
5	No ABG/CBG	96% (patient has ambulatory oxygen)	5.5.15	91%
6	No ABG/CBG	97% (patient has ambulatory oxygen)	26.6.14	93%

Table 1 shows the descriptions of all 5 patients who were known to the Home Oxygen Team

and the 1 patient who was referred into the Team

There was a wide spread of diagnoses within the 'potentially hypoxic' group of patients (figure 4). The two most common diagnoses were lung cancer patients and those with normal PFT's but no concrete diagnosis of dyspnoea.

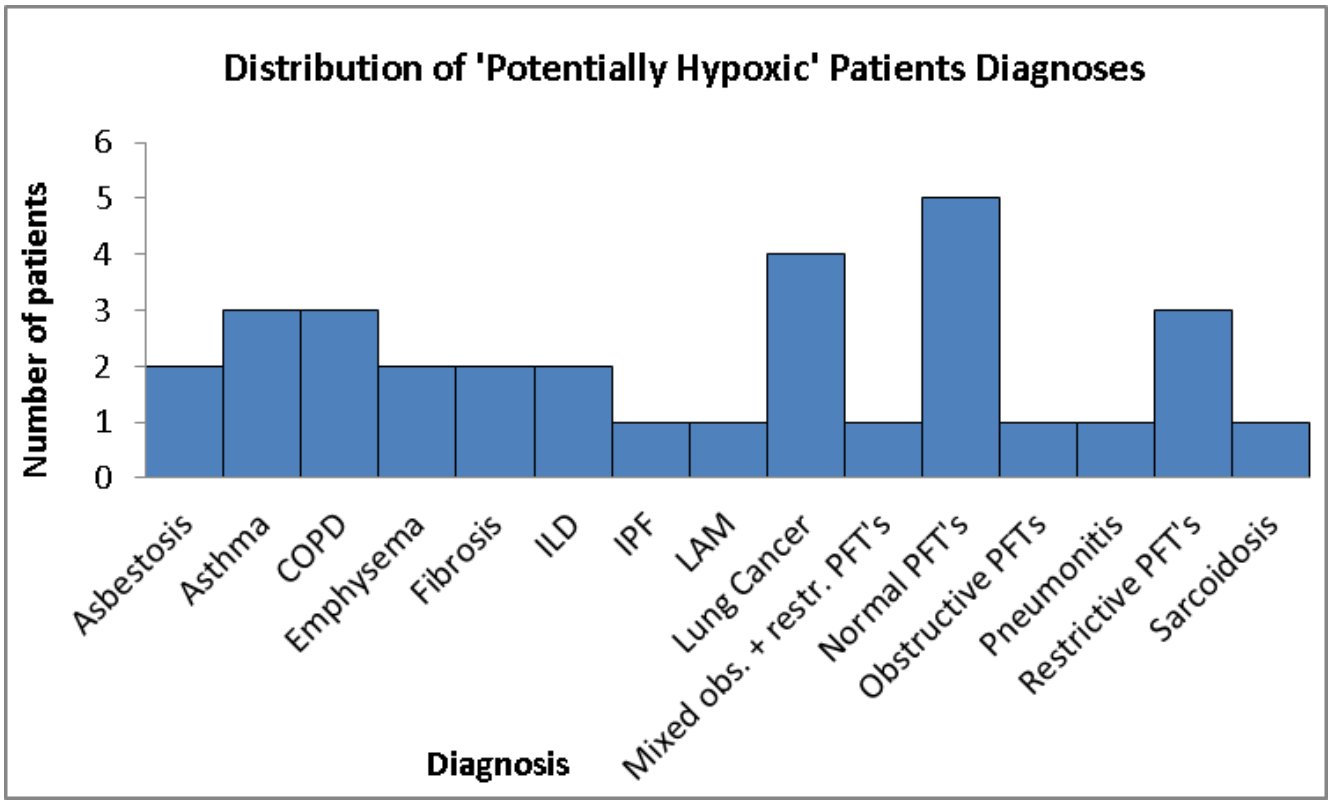

Figure 4 shows the distribution of diagnoses amongst the patients identified as 'potentially hypoxic'

Discussion

British Thoracic Society guidelines[2] state that patients with a $PaO_2 \leq 7.3$kPa should be prescribed oxygen to maintain a PaO_2 >8kPa. However, for patients who have secondary polycythaemia and/or pulmonary hypertension the threshold for oxygen is raised nearer to the normal range, to PaO_2 <8 kPa.

Due to the known inaccuracy of SpO_2 readings, a patient with peripheral oedema, with SpO_2 of 92±2% may still meet criteria for long term oxygen therapy (LTOT) as generally, an SpO_2 of 90% equates to approximately 8kPa [6] .

Bennett, et al., found a significant positive correlation between the SpO_2 recordings from a pulse oximeter and pO_2 recorded from ABG's in IPF patients[1]. The correlation was not altered with patients on supplementary oxygen either, therefore, it was deduced that SpO_2 monitoring was a suitable non-invasive method of assessing oxygen saturation. However, Van de Louw describes a 'poor correlation between SpO_2 and pO_2 in critically ill patients' [5]. The mean difference between SpO_2 and pO_2 in patients admitted to Intensive Care was 0.02% (SD 2.1%).

However, Van de Louw also stated that there were differences in accuracy between the manufacturers of oximeters and, unsurprisingly, in patients taking vasoactive drugs. From this study it was deduced that a SpO_2 >94% ensured a SaO_2 >90%.

In order to confirm or reject the requirement for LTOT, an Arterial Blood Gas (ABG) must be taken. Due to time constraints and technical skill this is only performed once the patient has been referred to the Home Oxygen Team. Not only would it be advantageous to perform an ABG on the patients with SpO_2 ≤93% to assess suitability for LTOT but if this could be performed prior to the referral to the Home Oxygen Team then it would limit inappropriate referrals.

CONCLUSION

For the most part, patients referred for PFTs have a recorded SpO_2 that would not suggest hypoxia. However, it would appear that conducting spot-check SpO_2 on patients may identify those requiring an arterial sample to distinguish whether an LTOT pathway is appropriate. This system can be implemented to ensure the appropriateness of Oxygen Team referrals and reduce waiting times for LTOT assessment.

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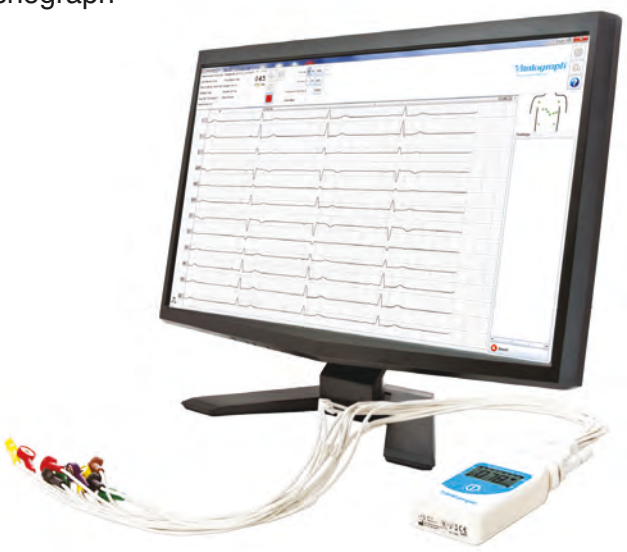

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A comparison of FRC equilibrium at 30s stability with FRC equilibrium at 60s stability using the helium dilution method

Shaun Baxter BSc, Edinburgh Royal Infirmary

INTRODUCTION

Lung volume by helium dilution is a routine test undertaken by a number of pulmonary function laboratories. Helium dilution is a technique that allows the measurement of functional residual capacity (FRC) which, with a vital capacity recording, enables the derivation of Residual Volume (RV), Total Lung Capacity (TLC) and other subdivisions of lung volume. Lung volumes are of interest to physicians in interpreting and monitoring pulmonary function and can improve decision making surrounding patient diagnosis, treatment, and disease progression.

Standardisation guidelines, and literature for carrying out lung volumes by helium dilution are widely available [1, 2, 3, 4, 5]. The overall technique has not changed and is based on gas dilution principles where a closed circuit system of known volume is filled with a known helium gas concentration. The subject is then introduced to the circuit at FRC; thus as tidal breathing commences, helium dilution occurs and continues until an equilibrium point is reached in gas concentration between spirometer and subject. Using gas law equations we are able to derive the unknown volume (FRC) from the known values as shown below:

$C_1V_1=C_2V_2$

$C_1V_1=C_2(V_1+FRC)$

$FRC= ((C_1V_1)/ C_2)-V_1$

where:

C_1= initial He concentration

C_2= final He concentration

V_1= System Volume

V_2= Total System Volume ($FRC+V_1$)

With advances in technology, equipment and software some changes in procedure may be possible. The stability period of no greater than 0.02% He concentration change for accepting FRC equilibrium (FRC_{eq}) is one area in which there is some inconsistency. Early literature has suggested a stability period of 2 minutes [6]. More recent guidelines, from the BTS and ARTP[7] suggest measurements recorded every 30s with two stable readings and therefore a stability period of 1 minute, whereas ATS/ERS [1] guidelines state measurements to be taken every 15s with two stable readings indicating a 30s stability period. FRC_{eq} at 60s stability (FRC_{eq60}) will not always occur 30s after FRC_{eq} at 30s stability (FRC_{eq30}) if He concentration is not maintained within 0.02%. If further dilution occurs greater than 0.02% then a new reference point for He stability is started until FRC_{eq60} criteria is fulfilled.

There is little guidance on FRC_{eq} stability time in patients with different disease processes or severity of dysfunction.

This study will investigate the accuracy of FRC_{eq} at 30s stability (FRC_{eq30}) compared with FRC_{eq} at 60s stability (FRC_{eq60}) in patients referred for full pulmonary function testing.

Methods

A retrospective analysis of FRC by helium dilution data was undertaken over a six month period (June 2014 - November 2014). Patient data was excluded if a system leak was either suspected or confirmed.

FRC measurement was carried out according to ARTP/BTS guidelines using Collins CPL pulmonary function testing equipment. Subjects were connected to the equipment and instructed to breathe tidally. After approximately 30s of tidal breathing the subjects were automatically switched in to the circuit at FRC. Tidal breathing commenced until He concentration was stable, with no change greater than 0.02%, for a period of 60s.

CPL software prompts the value of FRC_{eq30}, this value was recorded, dilution was then allowed to continue until ARTP/BTS guidelines for stability were fulfilled and this value was also recorded.

Evaluation of data was carried out using measures of location, spread and statistical tools where appropriate.

Results

Table one shows patient characteristics and standard deviations. 51% were male, 49% female. 53% had normal spirometry (43% showed an obstructive pattern and 4% a restrictive pattern).

N= 51	Mean	SD
Age	61.8	13.5
Ht.(cm)	166.7	8.4
Wt. (Kg)	75.6	17.8
BMI	27.1	5.7

Table 1. Patient characteristics

N= 51	FRC_{eq} at 30secs (L)	Time to equilibration (min)	Time to eq. corrected for 30s offset (min)	FRC_{eq60} (L)	Time to equilibration (min)
Minimum	1.52	1.75	2.25	1.56	2.25
25% percentile	2.44	2.50	3.00	2.43	3.35
Median	2.88	3.50	4.00	2.89	4.25
75% percentile	3.45	4.00	4.50	3.50	5.00
Maximum	4.99	6.25	6.75	5.23	7.75
IQR	1.01	1.70	1.25	1.07	4.30
Range	3.47	4.70	4.50	3.67	5.30
Mean	2.96	3.37	3.87	3.01	4.32
Standard Deviation	0.82	1.13	1.13	0.84	1.32

Table 2. FRC data descriptive statistics

From Table 2 we can see the similarities in the descriptive statistics for FRC_{eq30} and FRC_{eq60}. This is displayed in Figure 1 where we see little variation in location and spread of data values for FRC. This is further illustrated in the Bland-Altman analysis (Figure 2) where we can see bias is small (-0.04471) and 95% confidence intervals are narrow. Table 2 also shows total time to reach equilibrium for FRC_{eq} taken at 30 and 60 seconds stability. This shows a wider variation in location and spread of data values between equilibration times, less so when corrected for 30s offset. Figures 3 and 4 show that He concentration can dilute by greater than 0.02% after FRC_{eq30} is satisfied and this can lead to significant increases in equilibration times. This difference is reduced when corrected for 30s offset but remains statistically significant ($p<0.0001$).

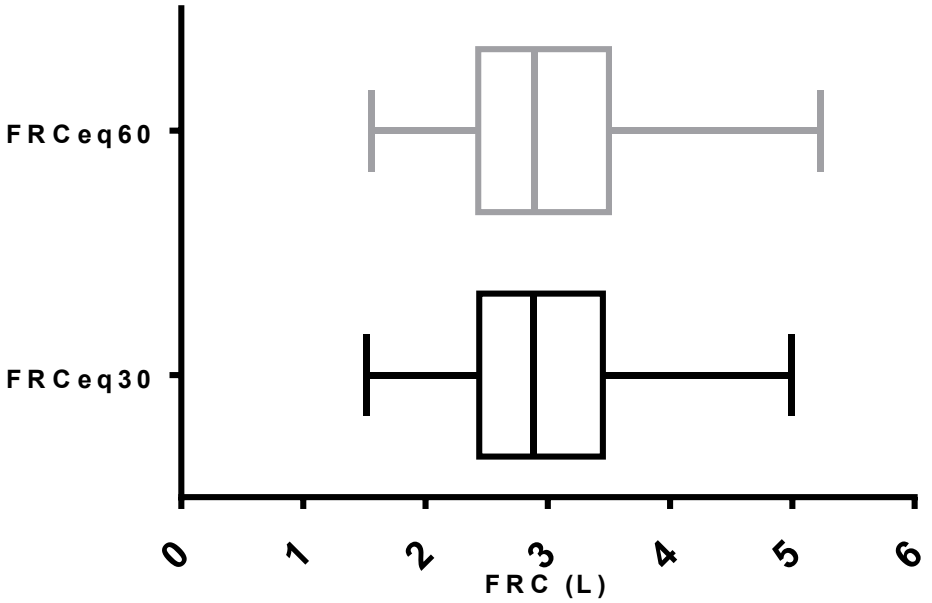

Figure 1: Boxplot of FRC at 30s stability and FRC at 60s stability

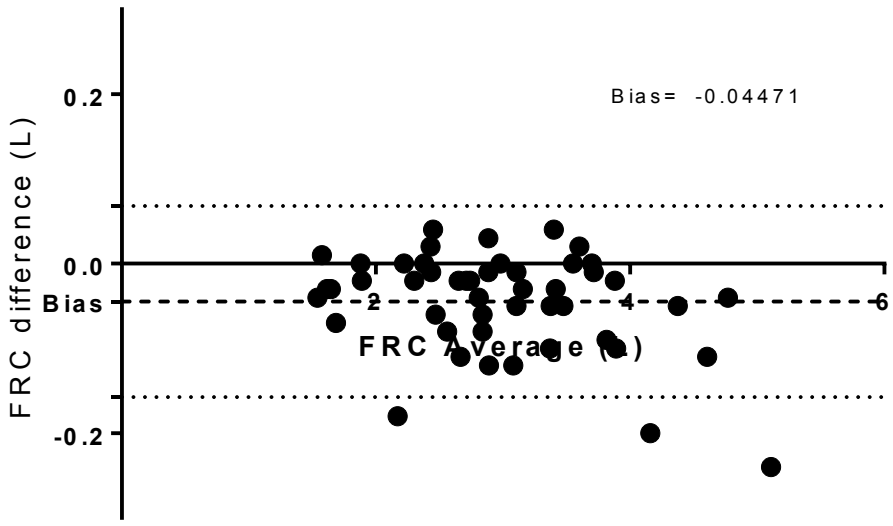

Figure 2: Bland-Altman plot: Difference vs Average of FRC_{eq30} and FRC_{eq60}

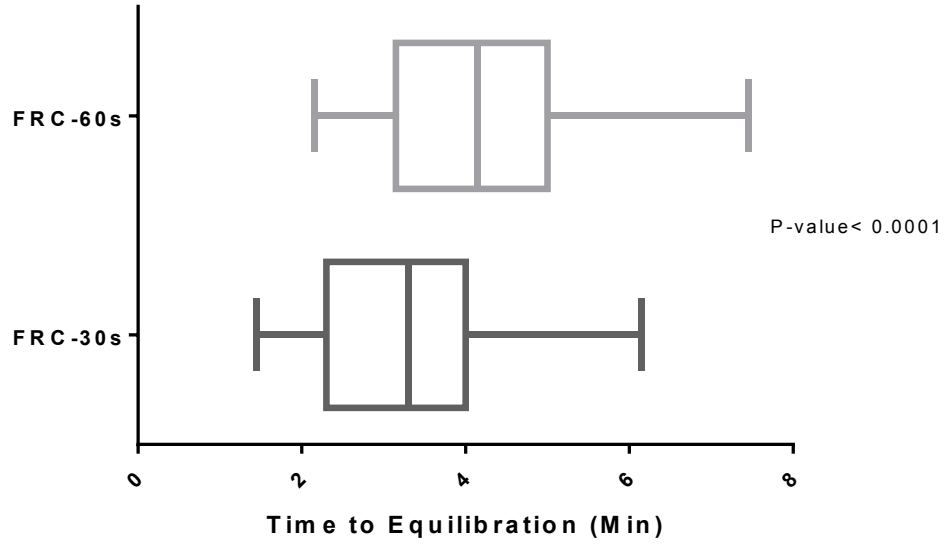

Figure 3: Boxplot of total time to equilibrium for FRC_{eq30} and FRC_{eq60}

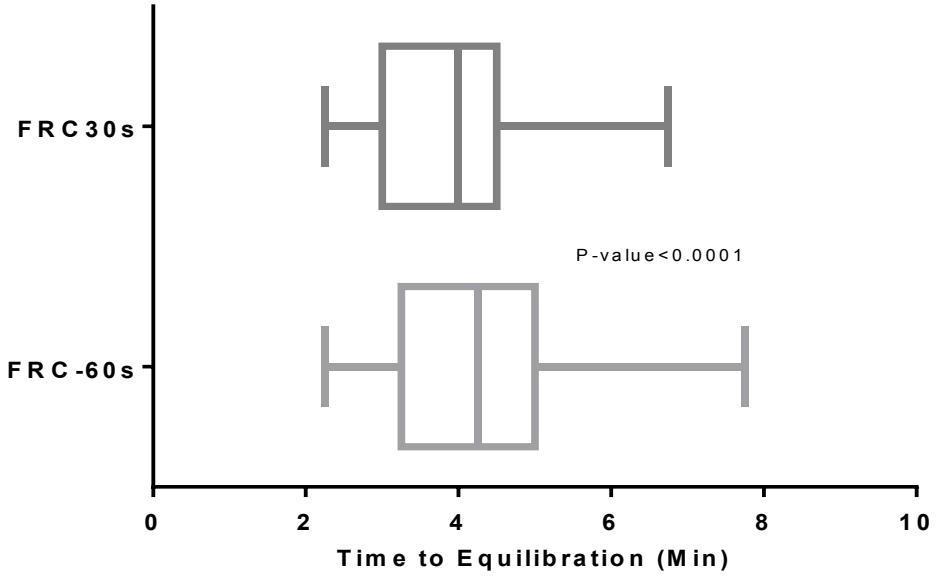

Figure 4: Boxplot of time to equilibrium for FRCeq30 (corrected for 30s offset) and FRCeq60

Discussion

From this study we can see there is negligible difference in FRC values when taken at 30 seconds stability or at 60 seconds stability even in subjects found to have significant airflow obstruction. Measures of location and spread for mean, median, 25% percentile, 75% percentile, and interquartile range showed small differences, of 50mls, 10mls, 10mls, 50mls and 60mls respectively. A wider difference, of 200mls, for the range and 240mls for maximum values was found. A mean difference of 50mls between FRC_{eq30} and FRC_{eq60} is not of clinical significance nor would alter overall interpretation of test data. This is supported by Bland-Altman analysis, which shows that the two different methods of accepting FRC equilibrium are essentially

producing the same result (bias= -0.04471). We can however see a significant difference in the time taken to reach equilibrium (p-value< 0.0001) between FRC_{eq30} (30s offset corrected) and FRC_{eq60} suggesting some dilution can continue after FRC_{eq30} is satisfied. The magnitude of this dilution has resulted in no clinically relevant difference in FRC. A longer test time can be more uncomfortable for patients with appreciable respiratory disease, increase chances of a system leak developing, and may increase waiting times for busy departments. If this can be avoided without compromising the quality of the measurement then it would seem appropriate, in keeping with ATS/ERS guidelines, to accept FRC_{eq30}. This study has found little evidence to suggest that accepting FRC_{eq30} will reduce the quality and interpretative value of the FRC measurement. The advancements in lung function testing equipment, gas analysers, computer software and use of rigorous Quality Control programmes has allowed for more comprehensive monitoring of helium dilution data. This, together with experienced and educated respiratory physiologists, has improved efficiency and reduced the need for longer helium stability times.

In conclusion this study finds no clinically relevant difference between FRC_{eq30} and FRC_{eq60} and therefore recommends using FRC_{eq} at 30s stability when measuring lung volumes by helium dilution.

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Half price launch offer for ARTP accredited spirometry course centres

The set-up of a pulmonary function and sleep laboratory in Nasiriyah, Southern Iraq

David Jones

Senior Respiratory Physiologist, Doncaster and Bassetlaw NHS Foundation Trust

The Ziggurat – a monument in the ancient city of Ur

Overview

I was asked by one of our respiratory consultants at Doncaster Royal Infirmary, Dr Mudher Al-Khairalla, to spend four weeks in Nasiriyah, southern Iraq, with the aim of setting up a functional pulmonary function and sleep laboratory, the first of its kind in Iraq.

The Hussein Teaching Hospital, Nasiriyah, where I was based

We faced many problems, unfamiliar equipment, language barriers, staff with no previous experience, no internet or air conditioning, no sinks or running water to the laboratory and short working days to name but a few. However, through a programme of practical and theoretical training we had staff performing full pulmonary function testing with relative autonomy, setting-up limited sleep studies and overnight oximetry, and setting-up patients on CPAP therapy after the four-week period.

We tried to condense my four-year training into four weeks and despite successfully setting-up the laboratory this was only the first step. Sustainability of the service is dependent on the Iraqi political and economic situation and this uncertainty could have a profound effect on its success in the future.

A view of the hospital from the roadside

Nasiriyah is on the Euphrates River about 225 miles Southeast of Baghdad and is the capital of the province of Dhi Qar (also called Thi Qar).

In 2003 the estimated population of Nasiriyah was 560,200, with the Dhi Qar region as a whole having a population of 1,742,852 [1]. The inhabitants of Dhi Qar are predominantly Shia Arabs, and they are among the poorest of all the governorates of Iraq, with 37.8% living below the poverty line [1].

The location of Nasiriyah in Iraq and the Dhi Qar (or Thi Qar) province

Introduction

The health service in Iraq remains centralised, focused on hospitals with primary care facilities in poor repair, inadequately staffed and disproportionately located[2]. Of the 2504 primary health care clinics that exist, over half have no medical doctor present. Tertiary centres such as the government funded Hussein Teaching Hospital, where I was based, are therefore found treating many patients that would, in the UK, be simply managed in primary care.

Patients with basic asthma are seen in tertiary centres or, even worse, driven to purchase unregulated over the counter asthma remedies, often laced with high dose steroids, and therefore are more difficult to manage when finally reviewed in tertiary care. Further to this the Iraqi Health budget is disproportionately allocated to projects in Baghdad – in 2010 this figure stood at 19%, and this is where the majority of health care professionals and hospital beds are based.

Doncaster and Bassetlaw Hospitals Foundation Trust serves a population of around 500,000 people, having around 10 WTE Respiratory Consultants. Compare this to the ThiQar region of Iraq, of which Nasiriyah is its capital, which has a population of greater than 1.7 million and currently has no respiratory consultants that are CCT qualified. Dr Al-Khairalla will be the first.

Until recently the future looked brighter, funding was released by the Minister for Health to fund projects such as the brand new respiratory unit at the Hussein teaching Hospital and a bariatric surgery unit based on the same hospital floor, on an adjacent wing. Unfortunately after the funding for the projects was released and the high specification equipment ordered, the situation in Iraq again became destabilised. ISIL (Islamic State of Iraq and the Levant) or Daish, as they are known in Iraq, entered northern Iraq meaning continued funding for new projects was significantly reduced, much of this funding being diverted to the front lines instead. I had the opportunity to sit and speak with Dr Saadi Al Majed, the head of the health department in the province of Dhi Qar and got the impression of a man who felt his hands were tied. Money was

needed in so many areas of the health service, not just in Nasiryah but in the province as a whole, however this essential funding was not available.

The need for sophisticated technologies itself is under debate, in terms of whether their use is efficient, and whether or not provision is in place for the maintenance and continued funding. Khadum (2013)[2] argues that the real national priorities should be focused around behavioural change around areas such as diet, exercise and smoking. These are things that Dr Al-Khairalla, along with the bariatric team are also keen to address.

The lack of an adequately functioning health system leads to as many as a quarter of the 1500 -1800 medical graduates each year leaving Iraq, predominantly to the UK, Australia or the USA[2]. In the UK alone there are currently 2390 Doctors registered with the GMC to practice medicine in the UK, who originally gained their medical qualification from Iraq[3]. Efforts to persuade Iraqi doctors to return have proven unsuccessful and cases like that of Dr Al-Khairalla and his colleague in bariatric surgery, Mr Akeil Samier, returning to Iraq are rare. Dr Thamer Al Hilfi argues that there are insufficient incentives or resources to encourage qualified doctors to stay; a result, he argues, of the health service not receiving a significant enough contribution of the Iraqi budget[4].

The Project

When Dr Al-Khairalla initially approached me about the project, several months earlier, I was excited by the opportunity and the potential difference we could make. He sold me the idea of developing a new Respiratory Unit with full pulmonary function and sleep facilities, where I would be involved, but he had also had a full ward refurbished and hoped to develop other services, such as pulmonary rehabilitation. My main concern was safety, on which point I was assured that in southern Iraq things were relatively stable, in fact the Dhi Qar region has had the lowest number of security issues in the whole of Iraq since 2008.

On arrival in Iraq we spoke at length about the project I was undertaking as we passed the oil fields of Basra on the horizon, on our way to Nasiriya. The plan was to set up a respiratory physiology laboratory, providing high quality pulmonary function and sleep diagnostics and sleep therapy. A big ask in four weeks!

My initial impressions of Nasiriya was of kind hearted and generous people who were extraordinarily grateful for my presence, embarrassingly so sometimes. I learnt the basics of hello and thank you in Arabic (As-salamualaykum and Shukran – if you ever need to know!), which I used as often as possible and people seemed to really appreciate. By the end of the four weeks I could perform basic pulmonary function testing in Arabic!

The pulmonary function equipment purchased included Cardiopulmonary Exercise Testing (CPET), Pulmonary Function Testing with body plethysmography, F_eNO, CO monitors, limited sleep studies and pulse oximeters, CPAP and BIPAP machines, with the associated download package. All of this equipment was new to me, and in addition I didn't have a great deal of experience with CPET. I arranged a few training sessions, whilst still in the UK, through the ARTP forum and got further training via Skype calls whilst in Iraq, which helped a lot!

The initial task therefore was setting up, and familiarising myself with the equipment before we could start the ground breaking venture of testing patients. We worked with local engineers and called in some favours from the UK to problem solve before finally everything was working effectively. Dr Al-Khairalla and I then sat down and put together a detailed programme of daily lectures and practical teaching sessions so we could try and ensure the doctors knew what was available and the staff I was training understood some basic theory too. The days agenda was simple, after calibrating the equipment we would see patients for lung function testing, followed by up to two hours of further training.

The staff work from 8.30 until 14.00 which minimised the practical testing time we had. It was important to get the balance right of covering the theory of all available tests without losing the detail of the most important tests. The reason for these short days is because

One of our many practical training sessions with the pulmonary function staff and doctors.

all doctors in Iraq are employed by the public sector, supplementing their income through private sector work in the evenings – which is paid for 'out of pocket' with no Iraqi health insurance available.

المركز العراقي للتداخلات المنظارية الرئوية
دائرة صحة ذي قار
مستشفى الحسين التعليمي

Respiratory Training Programme in Pulmonary Physiology and Diagnostics

Week	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Week 1 19-25 April	**Testing Equipment**	**Testing Equipment**	**Setting up**	**General Principles & Spirometry**	**DLCO**	x	x
Week 2 26 April-2nd May	**Static lung Volumes** (Plethysmography & Nitrogen washout)	**Sleep diagnostics** (Nocturnal Pulse Oximetry & Limited polysomnography)	**CPAP**	**Bi-Level Non invasive Ventilation**	**FeNO CO monitoring Peak Flow Monitoring**	x	x
Week 3 3-9 May	**Muscular weakness testing**	**Blood Gas & Hypoxic Challenge test**	**Field Exercise Tests** (6MWT, Shuttle & Ambulatory Oxygen)	**CPEX 1**	**CPEX 2**	x	x
Week 4 10-16 May	General session for **Baghdad** colleagues 1	General session for **Baghdad** colleagues 2	**Case Study 1**	**Case Study 2**	**Case Study 3**	David travels back to UK	x

Each session is between **1100-1300** in the pulmonary physiology laboratory

The training plan devised by me and Dr Al-Khairalla for my 4 weeks in Iraq

I was initially working with two members of staff, Fatima, a qualified nurse, who spoke reasonable English, and Hussein, a Health Care Assistant. His English was limited and I was to rely on translation from Fatima predominantly. Dr Al-Khairalla and I were also training three doctors with a specialist interest in respiratory medicine who would be working on the unit, they were enthusiastic and eager to learn about the new tests and treatment they could offer.

One of the first problems we encountered was that the department had no functional air conditioning making it very hot and uncomfortable in the laboratory, not to mention the uncertainty it produced about the accuracy of the pulmonary function results. Due to the lack of available finance in Iraq, continued funding for things such as this, the internet and consumables becomes a real problem. The reasons given to me for this were numerous: corruption, endless bureaucracy (that corruption can help avoid!) and the fight against terrorism in the North being very expensive, placing a huge burden on the finances of the health sector. We did finally get working air conditioning, about 3 days before I left!

The effect of the lack of financial resources in Iraq became evident very quickly. The hospital had no working blood gas analyser – they had three, but one of the reagents they required for their use had expired and they had been unable to get funding to replace it. This is a tertiary centre equivalent for a city of more than 560,000 people, that was capital for a region of more than 2 million.

A main problem I encountered was an obvious one, the language barrier, and how much longer the teaching process took with interpretation involved – not to mention testing patients! The main step I took was through the addition of a new member of staff who spoke good English and was enthusiastic about the project and where it could lead. After a brief discussion with Dr Al-Khairalla we agreed he was what the laboratory needed. This gave us a real lift, he provided the translation and was really receptive and good with patients.

During the four weeks I wrote simple step-by-step guides for all the pulmonary function tests, CPET and for CPAP set up, and reviewing CPAP downloads (see overleaf). I also left behind some key texts, the ARTP Part 1 (2003), Kinnear's (2007) - Lung Function Tests: A Guide to Their Interpretation, and John West's Respiratory Physiology: The Essentials (2012) and Pulmonary Pathophysiology: The Essentials (2012).

Four weeks was obviously a very short time to develop a basic technician never mind a 'complete' physiologist in pulmonary function and sleep, after five years I'm still learning new things all the time! It was therefore important for me to give those working in the lab the ability to take some autonomy after I left. I stressed the importance of reading, and asking questions both of me, and of the manufacturers to increase their knowledge of the equipment and the test they are performing and hopefully one day interpreting.

One of the worries is staff retention. Staff are paid poorly and their quality of life in Iraq can be poor also. A couple of the members of staff discussed with me the possibility of being able to leave Iraq to find a better life in Europe. The problem with this is that Iraq really needs these people to stay and help rebuild the infrastructure and health service. I urged them to stay and help set this service up before they considered a move away.

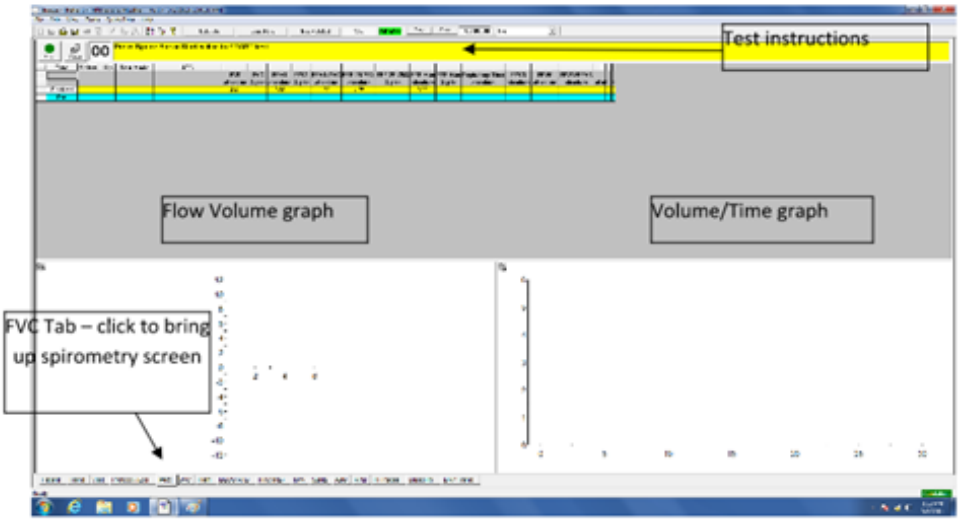
Performing Spirometry (FVC)

Before beginning a spirometry please refer to the guides 'Initial Set up and Calibration' 'Creating a new patient' and 'Attaching the flow head and mouthpiece'

STEP 1

Click the 'FVC' tab (Forced Vital Capacity) to bring up the screen for performing spirometry. On the left you will see the Flow/Volume graph. On the right you will see the Volume/Time graph.

The yellow bar gives step by step instructions on how to perform the test.



STEP 2 – Give the patient basic instructions for the test

Explain the test to the patient as simply as possible and demonstrate the technique to them.

1. Begin with normal breathing
2. Take a deep breath in until your lungs are full

An example of the step by step guides I wrote for each and every test

A large number of patients that we were seeing in the laboratory were patients with extremely poorly controlled asthma and COPD. As previously discussed, the lack of appropriate primary care in Iraq means that these patients end up presenting in the hospital setting, only once significantly unwell. The city of Nasiriyah, much the same as many areas of the Middle East, is subject to dust and frequent dust storms. The effect of these dust storms was investigated in Kuwait by Thalib and Al-Taiar (2005)[5], who demonstrated that on days with dust storms events, respiratory and asthma hospital admissions were significantly increased. A contributory factor to this is likely due to Iraqi dust containing titanium and other heavy metals and microbes, as well as sandstorms producing sharp-edged particles at densities much higher than those deemed safe by the US Environmental Protection Agency, who also argued that a significant contributor to the asthma and COPD prevalence in Iraq is the poor air quality, with the number of

An example of the traffic jams on the road outside Al Hussein

vehicles on the road having rapidly increased in recent years[6].

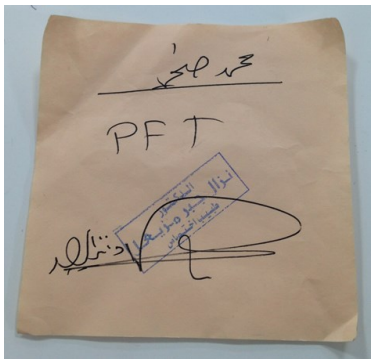
The prevalence of heavy smoking is also very high in Iraq. I witnessed staff smoking in side rooms on the respiratory wards! Further exacerbating the problem is the lack of appropriate diagnostic and therapeutic support – which is hopefully where the unit will help.

Obesity is growing in prevalence in Iraq[2] and on an adjacent wing a team of surgeons and anaesthetists, originally from Iraq but working in the UK, were setting up a bariatric surgery unit. The more patients they saw, the busier our sleep service got, as I am sure you can imagine! We managed to diagnose and perform an initial two night CPAP initiation on a number of patients and are currently looking at

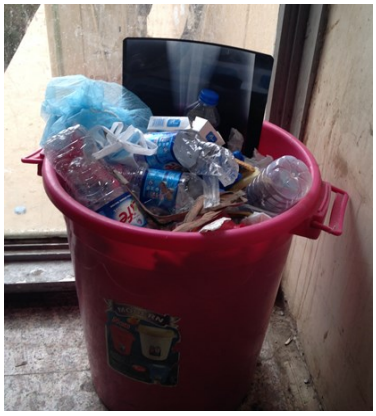
The first ever patient set up on CPAP therapy in Nasiriyah

a cost effective solution to enable patients to buy their own machines.

Patient identification was a real problem. Patients did not have a hospital identification number, their name was in Arabic and had to be translated, and to top it all, a large number of the older generation did not even know their date of birth! This may come as a shock, but it's not something that was recorded vigilantly and as a result the information has been lost. Due to this we found a large number of patients with 1st July as their date of birth – this is the date of birth given to everyone who does not know it. This makes pulmonary function predicted values even more inaccurate! The referral forms we received, initially on post-it notes, held no clinical information to aid with the test required – a new referral form was one of the first things I implemented and distributed.



Before I implemented a 'referral form' this is what we received



Patients are required to look after their own hospital notes and test results. Some obviously don't make it home with them!

During my stay in Iraq I was lucky enough to be given the opportunity to visit some amazing places most won't ever get the chance to see, the bustling market centre of downtown Haboubi where many doctors run their private practices, the ancient Ziggurat monument from 21st century BC (see front page) and to visit Dr Al-Khairalla's dad in Rafai where I got to try local food, and play a huge game of football with many of his relatives.

Probably the best trip, however, was to the marshes of southern Iraq where a group of around twenty from different departments in the hospital went out on boats and afterward were served a traditional meal of fresh smoked fish.

A stop en route to the marshes with a group from the hospital – I was well looked after

The beautiful marshes of Southern Iraq

Me and the team (most of them!) on my final night in Iraq

Final Remarks

As I prepared to leave Iraq my parting thoughts were for how lucky I am. Lucky, not just in the sense that I have a clean and safe healthcare system with doctors available 24/7, but in how the opportunities I've had in life have enabled me to have a good education and find a good job with security. Dr Al-Khairalla and I were comparing my life with some of the staff in the laboratory who are my equivalents but are limited by their opportunities and quality of life.

In the time it has taken me to write this article, Dr Saady Al Majed has been relieved of his position as head of the health department in the province. The repercussions of this for Dr Al-Khairalla and his team remain to be seen and leave them with an uncertain future. Dr Al-Khairalla and the people of Iraq have to deal with uncertainty on a daily basis, therefore this is nothing new to them. It is yet another battle, but a battle I am sure they are capable of winning.

In Iraq they have a commonly used phrase – *'In shallah'* – it means 'God willing'. I heard it used many times related to our project because of the uncertainty we faced. One day I will return and find a developed pulmonary function unit that is helping provide effective diagnostic and therapeutic support, 'In shallah!'.

Please feel free to follow the development of the project by liking the 'Breathless in Iraq' facebook page (https://www.facebook.com/breathlessinIraq).

Acknowledgements

I would like to thank everyone at the ARTP who offered support and advice for my trip to Iraq, especially Nick Chapman at Medical Graphics UK and Selwyn Sher at S-Med Ltd who offered me excellent support even whilst I was in Iraq. Finally and most importantly I want to thank Dr Mudher Al-Khairalla, who gave me the opportunity to be involved in this project and looked after me so well whilst I was in Iraq.

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Nigel Clayton
Brendan Cooper
Alan Moore

ON THE BLOWER

In this edition of On the Blower we have the usual company round up and details of the ERS POINT awards. As you have probably noticed, I am still here acting as Chair of Manufacturers Liaison and we are still seeking a deputy to cover this role with the view to taking the reins as Chair. I have thoroughly enjoyed acting as Chair of Manufacturers Liaison over the last 16 years and would not have committed all these years had I not enjoyed it. There are some perks to the job and if you are interested and would like to know more, please contact me by email or give me a call on 0161 291 2406. You will find a brief overview of the role at the end of this article.

Company Round-Up—with clickable manufacturer links

DeVilbiss

I'm sure many of you are already aware that Drive Medical recently acquired DeVilbiss Healthcare from Vestar Capital Partners in July this year. In the short term, Drive and DeVilbiss will operate independently as they work to integrate the two companies in the Americas. Upon completion of the integration, the new company will be known as Drive DeVilbiss Healthcare, Inc. In the rest of the world, Drive and DeVilbiss will continue to operate as independent entities, so hopefully we should not see a great deal of change. As you would expect, Drives ambition is to build on the DeVilbiss brand and product line to make them the respiratory and sleep market leader.

In the early days CPAP machines were simply blower motors set at constant pressure with no adjustments in pressure between inspiration and expiration. The goal these days is to produce pressure algorithms which detect events and respond to them such that the patient has a comfortable and effective nights sleep. The DeVilbiss Blue CPAP machine has been developed to the extent that it is now possible to detect and report hypopnoea, obstructive apnoea, leaks, flow limitation, RERAs, central apnoea and periodic breathing. Optional pulse dose humidification is another innovative feature which is designed to deliver heated humidification only on inspiration. This helps conserve water and eliminates "rain-out" within the tubing. Connectivity allows remote monitoring and adjustment of the device which also has the capability to record pulse oximetry if required. Apart from cleaning and filter changing the machine is said to be maintenance free for its lifetime. NC

Vitalograph

The new Vitalograph micro spirometer has recently been launched and comes in at a respectable price of around £560 (including VAT). The colour touch screen makes it easy to use via icon driven software and provides a clear display of real time flow volume and volume time graphs. The removable fleisch flow transducer enables true calibration and easy cleaning.

Included with the spirometer are a carry pouch, USB lead and a disk with Vitalograph Reports to enable the creation of pdf reports. The unit is powered by standard AAA batteries, however, the USB lead can be used to power the device when connected to a PC. The Vitalograph Reports programme is new for the Vitalograph micro but will also function with the Alpha, In2itive and 4000 series.

A range of race groups/predicted sets can also be selected in the new micro, including the latest GLI predicted values. NC

CareFusion

In the previous edition of "On the Blower" we mentioned new additions to the UK CareFusion RDx team. The latest recruit is Mark Evans who joined CareFusion in July as the new IT/Connectivity Specialist. I'm sure many of us will be calling on Mark to resolve the ever changing network issues we have within our trusts. NC

ResMed

Following Ewan Cuthbertson's transition to the UK MD role, ResMed have now recruited a new Commercial Manager, David Jones. David has many years' experience in the Pharma industry so is familiar with the world of the NHS. He's spending time out and about with the Account Managers at the moment so many of you will no doubt meet him ahead of BSS and ARTP conferences.

Following the completion of the Serve-HF clinical trials of ASV in predominant central sleep apnoea in patients with symptomatic heart failure and reduced ejection fraction and its subsequent field safety notice ResMed have been analysing both the primary dataset as well as the additional data collected as part of the sub-study.

In excess of 1.3M data elements were collected throughout the 7 year study and the statisticians and researchers are now carrying out extensive data mining in order to start the process of understanding the potential mechanisms behind the result as well as to look for any potential signals that might identify a group of patients at particular risk.

Initial publications of the findings have been submitted and can be expected to be presented

at the European Society of Cardiology (London) in August and then at subsequent major conferences including the European Respiratory Society and American Heart Association

May also saw the launch of Lumis™- a range of non-invasive ventilators designed for non-dependent patients with respiratory insufficiency. Lumis provides a new entry-level option for care providers to manage the respiratory stability of their patients alongside the Stellar and Astral lines in ResMed's respiratory care range. Lumis is built on the same platform as the AirSense 10 and AirCurve devices, and offers new features that improve the ease of use and patient customization, along with wireless connectivity. NC

Ticks all the Boxes and a Great Offer

Over recent years we have seen some poor spirometers and associated software come out of Italy, Spain, Germany and countries further afield. Intermedical has just announced the launch of their next generation desktop spirometer. They have been working with M.I.R. in Italy and listening to potential customers in the UK to produce what they claim is a class leading device designed specifically for the UK market. Now that is some claim to make, so how does it stand up?

Well, in terms of features, the new Intermedical Spirolab has a large 7 inch high definition colour touch screen allowing users to clearly see real time graphs and configurable numeric results, including LLN and Z-score (same as SR). GLI reference values are also on board. Considerable thought has gone into the design of the device to make it easy to use for even the most basic user. With large on screen icons, the operator can navigate easily through the intuitive options. It allows Relaxed VC and either expiratory only or full flow/volume loop measurements to be performed. The device can be used either from mains power or the rechargeable internal battery that provides several hours of use. This new Spirolab is compact and very portable and so is equally at home in the hospital clinic or at bedside as it is in the community setting. It features

large storage memory and a fast, on-board high definition printer. Test results can be saved and viewed later on-screen or printed out at the touch of a button.

It's not often that we heap lots of praise on a new device but this one is, in our opinion, exceptional. Intermedical are to be congratulated for taking a device from a renowned manufacturer but whose onboard software has sometimes not been the most intuitive and turning it into what we can only describe as an excellent device, ideal for the UK market. Couple this with the fact that M.I.R. also offers pre-calibrated, low cost single patient use turbines to go with this device and you have a combination that is a rival for the other turbine spirometers on the market.

The list price is towards the top end at £1,245 (plus VAT). However Intermedical is making a special introductory offer of a 50% discount to ARTP-Accredited Spirometry Training Centres. That is an excellent offer and one that we felt Manufacturers' Liaison should bring to the attention of the membership and other spirometry manufacturers. **AM/NC**

Clarity on Spirometer Calibration/ Verification

It has been brought to our attention recently from a variety of ARTP members and nurses on ARTP spirometry courses, that several renowned spirometry manufacturers are still claiming their devices "do not need calibration or verification". Some also claim that their disposable flow sensors are pre-calibrated and do not require checking. Can we make it absolutely clear that although some devices cannot be truly "calibrated" (i.e. tested with a calibration syringe and adjusted to read an exact volume), ALL spirometers, no matter what their principle of operation is, should have their volume "verified" (i.e. tested with a calibration syringe and checked that they read within an acceptable tolerance) at every testing session or when conditions change significantly. If calibration is possible it should be undertaken, checked and just like any verification, recorded in the devices quality control log at that testing centre. Advice other than this is not only unscientific and against international professional guidance, it is also dangerous and puts patients at risk of under/ over diagnosis of lung disorders. Further reports of "no need to calibrate" will be "named and shamed" in On the Blower. **BC**

ERS Product of Outstanding Interest Awards 2015

The 2015 ERS Congress is starting in Amsterdam on Saturday 26th September until Wednesday 30th. For 3 years the **Product of Outstanding Interest (POINT)** sessions have attracted great interest from both clinical members and corporate participants attending the Congress. The session is usually diverse, entertaining and a break from the usual didactic presentations of the main sessions. The finalists will also take part in an interesting and exciting programme of the POINT Award for 2015.

The European Respiratory Society has created this award to recognise the importance of innovation in medical device diagnostics and therapeutics in respiratory medicine and to reward those whose efforts have led to such advances. The award is partly aimed at encouraging new innovation and application of current ideas into solving the challenges of modern respiratory healthcare, but also to raise the awareness of ERS members as to what is new, ground-breaking and important in the respiratory market place.

This year the POINT process started at the ERS Congress in Munich, with manufacturers and Heads of ERS Assemblies and ERS members able to submit products to go forward for POINT 2015 nomination procedure. There were nearly 40 nominated products which were short-listed by the POINT Panel down to 4 devices. At the POINT session on Tuesday September 29, 2015 from 13:15 to 14:30 in room D201-202, the panel will award 2 prizes, one for a diagnostics and one for a therapeutics device respectively out of the 4 finalists. It is difficult to decide a winner because all the finalists are winners by virtue of the fact they are in the POINT session but it is also the taking part that matters and as usual there have been many good nominated devices that capture the spirit of the POINT award.

Device	Company	Website
Diagnostic		
Apollo®	VIDA Diagnostics	http://www.vidadiagnostics.com/solutions/APOLLO.htm
Pocket Air Tube	Microbase Technology Corp	http://www.microbase.com.tw/aerosoltheraphy/pocketairtube.html
Therapeutic		
Sleep Position Trainer (SPT)	NightBalance	http://www.nightbalance.com/introduction
Smart One	MIR Medical International Research	http://www.spirometry.com/ENG/products/smartone.asp

POINT Diagnostic Finalists, 2015

The websites for the devices are also available, so all ERS members can look at their leisure during or after the Congress.

The key features of the finalists are summarised here;

1. Apollo® from VIDA

VIDA provide software services for the analysis of chest images by CT and MRI. This allows clinicians to focus more on their patient instead of a computer monitor. Cases are sent to VIDA for on-demand analysis and the results and report are returned to you in 3 business days. Faster turnaround is available if required.

There is an Analysis Quality Control and the company is an ISO 13485 certified organisation which follows strict quality controls. Image transfer is secure and safe, either electronically via the web or portable media. There is an option to anonymise cases before transfer. Alternatively, Apollo software is installed at the site as a yearly license for your review and interaction of the analysis results.

2. Smart One from MIR

MIR has been producing turbine spirometers for many years. What's attractive about this concept is the connectivity via Bluetooth or Smartphone so that patients can (with some training) learn to use personalised spirometry to monitor their condition or treatment. This device is targeted mainly at lung transplant patients (to detect early signs of rejection), and for monitoring interventions (Asthma, COPD, Cystic Fibrosis) and for use in Clinical Trials. Clearly, this concept for "monitoring" spirometry has its place, but should not be confused with quality diagnostic spirometry.

3. Pocket Air Tube from Microbase Technology Corp

This is a novel palm-sized, single patient use, nebuliser for inhaled aerosol therapy which is capable of producing a fine particle (MMAD <5µm), low velocity aerosol that is optimised for targeted drug delivery and is comparable with conventional nebulisers. Its big advantage is that it is noiseless, has a low residual volume (<0.1mL) and it doesn't heat or degrade the medications. Furthermore, it can work off a USB port, portable battery pack or through a mains adaptor, so it is highly flexible for the patient on the move. It's output is around 0.25mL/minute, so a 6mL fill will take about 24 minutes to administer. There are no independent peer-reviewed publications of the device available yet.

4. Sleep Position Trainer (SPT) from NightBalance

Since we're in Amsterdam, it's good to see a Dutch POINT finalist, NightBalance. Their simple device is designed to overcome the problem of positional Obstructive Sleep Apnoea/Hypopnoea Syndrome (POSAS) and snoring. The device is made up of a position sensor which determines when the patient is supine and then gradually and comfortably trains patients using gentle vibrations to not sleep on their back. The SPT is small, it is comfortable to wear and the patented technology ensures tolerable yet effective treatment. It is worn around the chest with an

ergonomic strap and continuously measures personal sleep behaviour and on the basis of this information gives a light vibration at necessary times to encourage change of position. There are no independent peer-reviewed publications of the device available yet.

ARTP Manufacturers Liaison Committee has looked at having a similar scheme to POINT for ARTP members. The idea is to select any product that shows innovative flair, a clever use of technology, but ultimately something that makes a large difference to patient's lives by either better diagnostics or a new therapeutic device. We haven't taken this forward, but would be happy to hear your enthusiasm for such an Award for ARTP manufacturers. Please contact us via ARTP Watchdog.

If you're lucky enough to be going to ERS Congress in Amsterdam we look forward to seeing you at this year's POINT session. We have an interesting and entertaining programme with a theme based on "Top Tips" for bringing medical devices to market, taken from advice from previous POINT Finalists. We will also be discussing medical devices legislation and what it means for you and your patients in the future.

N.B. This article is taken directly from the ERS Respiratory Equipment Directory (RED) being launched at conference. All copyright remains with ERS but is used here with permission.

BC

Encryption Confusion

How many of you know whether the database associated with your lung function testing system(s) is encrypted? If you don't know the answer to the question, perhaps those of you who are Heads of Service should make enquiries from your supplier and find out. There is a good reason for this. It is now perfectly feasible on switching equipment supplier to transfer your patient data into your newly supplied system. There are at least two companies who can import patient data from a rival system and may also be able to import graphics from some rivals. It is perfectly possible that other suppliers can do this also.

There could, however, be a snag. That snag is when your current supplier has encrypted your patient database. They may well have done this without your permission and for no legitimate reason within the UK. So, has your database been encrypted by your PFT equipment supplier? If so, did you give approval for that encryption to be applied to your patient database? Do you have a signed document indicating that your Trust has given its approval to the equipment supplier for the encryption? I suggest you find out the answers to these questions.

In 1996, the United States Government enacted legislation, the Health Insurance Portability and Accountability Act (HIPAA) which had a similar rationale to the UK Data Protection Act in terms of confidentiality of patient data. One solution to this was to encrypt the patient database and, in the case of SensorMedics' VMax and Jaeger's JLab, this was the solution to the American legislative problem. However, no such encryption requirement was or has ever been required by the requirements of the Data Protection Act in the UK. How your Trust or Health Board protects the data it has stored is up to them.

On 30th March of this year, **ARTP Watchdog** was contacted by a Head of Service requesting information and assistance. In the letter the user stated:

"I have encountered problems with the transfer of data (to allow for serial reports spanning both kits) from my [current] PFT system across to our newly purchased [different supplier] PFT system. [My current supplier] are telling me that they can't unlock the data (and that they have never heard that it can be done!!) ……..."

ARTP Watchdog contacted the Sales and Marketing Manager of [the company concerned] on behalf of the Head of Service on 18th April. In this letter we stated that:

"H.I.P.P.A. legislation is a piece of American legislation that has no legal force in the United Kingdom. The Data Protection Act in the United Kingdom requires that patient data be stored securely. It does not require or even suggest encryption of data".

Watchdog also stated that:

"It is possible to transfer the data from an unencrypted [PFT] database to that of a rival supplier. The same also applies to unencrypted [Company] databases….. All it requires is to not activate the encryption option on creation of the database at installation".

12th May. A holding email was received from [Company] explaining annual leave, etc.

21st May, a further holding email received. In the interceding period there has been a full and frank telephone conversation where I have advised [Company] that the solution to an encrypted [PFT] database is for them to provide the client with a version of the 'Open Database' option.

12th June arrives and still no further forward. A further holding email is received from [Company]:

"Apologies that there has been no update regarding the unencryption of the [PFT] database. The person who has been dealing with this has gone off on maternity leave and I have only recently had to bring a second person up to speed with the situation, I appreciate that this is not your fault but this has been the reason for the recent delay".

23rd June and:

"Following on from further internal discussions this week I am extremely pleased to confirm that we can begin to look at the process of unencrypting your [PFT] database containing your patient data. There is some documentation that must be prepared along with a quotation, so please bear with us during this period. After some discussion with xxxxxx (Head of Service's Line Manager), xxxxx has kindly nominated herself as first point of contact and as such the paperwork and quotation will be addressed to xxxxx.

Please accept our sincere apologies in the length of time it has taken to reach this solution, but [Company] fully agrees and supports that this is the best outcome for you, and ultimately the patients you support. In the meantime if you have any further questions or queries, please do not hesitate to contact me directly".

So, some 2 months after the initial communication from the Head of Service, [Company] acknowledge that the database can be unencrypted. In the interim, the Head of Service's Line Manager took over discussions with [Company] and appears to have agreed to pay for the unencryption to take place. I personally find it shocking that [Company] appear unwilling after a 2-month delay to waive payment for the unencryption.

The Moral of the Tale

1. **Don't allow an equipment provider to encrypt your patient data unless you want hassle if you decide to choose an alternative equipment provider.**
2. **Write it into your tender specification that the patient database must not be encrypted.**
3. **ARTP actively discourage the encryption of any data without the express permission of the purchaser/owner of the data. Customers should be allowed to have data "un-encrypted" free of charge. If companies ignore this advice in order to bolster "brand loyalty", then ARTP will consider reporting companies for being anti-competitive through their regulatory bodies.**

Footnote

Even though [Company] now use a SQL database, encryption of the database is still the default option from this company. A true SQL database is never encrypted. You have been warned. AM

Vacant ARTP Committee position

Deputy Manufacturers' Liaison Officer

Do you feel you could make an excellent ARTP/ Manufacturers' representative who would enjoy liaising with the companies we all deal with on a day to day basis? We are looking for a person to deputise in this role with a view to taking on the position of chair. The position requires approximately 2 hours per week of your time and includes the following duties:

- To meet with manufacturers' / suppliers to discuss problems reported by the association membership as and when required.
- To liaise with the membership and Medicines and Healthcare products Regulatory Agency (MHRA) with regard to risks associated with equipment used by the membership.
- To act on equipment / service issues raised via the ARTP "watchdog" forum.
- To compile "On the Blower" for Inspire.
- To act as association representative for the manufacturers' at the annual conference.

To conduct an annual survey of the membership concerning equipment quality, sales and service and to report the findings to the membership and the manufacturers'.

In addition to the above duties you will also be expected to attend 2-3 Standards Committee meetings per year at ARTP headquarters.

For more detailed information please call Nigel Clayton on 0161 291 2406 or email nigel.clayton@uhsm.nhs.uk.

Complaints

Don't forget, if you have any problems regarding equipment malfunction, quality control / calibration, service response times, software issues etc. please feel free to voice your opinions off the forum by contacting the Manufacturers Liaison Committee direct at Watchdog@artp.org.uk. We will then be able to collate this information, including verification of accuracy, before commencing on an appropriate course of action.

Finally, to all the manufacturers who may be reading this article, please remember to keep us posted with details of any new products you are about to release on the market. Details should be sent to nigel.clayton@uhsm.nhs.uk or stuart.wragg@aintree.nhs.uk.

What is involved in being an ARTP examination Centre?

Sandra Davies, Chair of Examination Standards

The new ARTP Associate and Practitioner examinations are held in the Spring and Autumn times. The ARTP is always looking to attract new testing centres in order to offer a greater variety and choice of equipment to the Candidates.

If **your** centre was to commit to host the examinations, what would this involve, what are the benefits, what credentials would an examiner require?

Your centre would agree:

- To have a pool of local Examiners. (Technical and Clinical Assessors)
- To have a Co-ordinator (this could be a Physiologist or an Administrator) who:
  - Arranges room availability
  - Arranges patients availability
  - Establishes a timetable for the assessments
  - Liaises with the candidates to confirm their assessment times
  - Provides the candidates with travel and accommodation advice
  - Arranges for the candidates to visit the centre in advance of the examination

The Benefits for your centre include:

- Financial - payment for your Centre, Co-ordinator and Assessors
- Professional - Showing your support for OUR Examinations
- A good opportunity to be at the forefront of education and evaluation of the new Healthcare Practitioners and Scientists

The Examiner(s) must:

- Hold a BSc in Clinical Physiology or equivalent
- Have a minimum of 1 year postgraduate training and continuation in the field
- Be an Accredited member of the ARTP
- Be registered on the RCCP or HCPC register
- Undertake the ARTP examiner training course and refresher course every 2 years

- Observe at least one ARTP examination
- Commit to examine at least once per annum
- Abide by the ARTP examiner code of conduct
- Have undertaken equality and diversity training in the past 3 years

I wonder if your Department would be interested in becoming an Examination Centre?

I am particularly keen to attract centres for October 2015 with access to the following Lung Function equipment:

- Carefusion Sensormedics Vmax 22 Encore software 21-2A Nitrogen washout
- Nspire Zan Body Plethysmography

If you are interested, please download the application form to apply for exam centre status, or contact me if you have any questions.

Sandra Davies

Chair of Examination Standards,

phone | ffôn : 01685 728403

Email: Sandra.Davies4@wales.nhs.uk

CLARIFICATION OF STANCE FOR E-CIGS/VAPES IN VIEW OF NHS ENGLAND STATEMENT

...Am I correct in my understanding in that none of these e-cigs/vape units have been medically tested in the UK by any official body i.e MHRA for safety or content…? **Lou Renwick, Royal Surrey County Hospital**

ARTP has arranged a session on this very subject for its 2016 conference which will prove very informative. My advice would be to listen to the speakers we have arranged and form an opinion based on the evidence they present. **Alan Moore, Chair, ARTP Events Committee**

My advice to patients continues to be don't smoke anything. **Adrian Kendrick, University Hospitals, Bristol**

Kimberley Lewis of Milton Keynes University Hospital posted:

Here is a summary of what I found. Please be aware, the evidence is sporadic, unclear and it is difficult to access quantifiable data:

This is a complex issue which has split Healthcare professionals. E-cigarettes, E-cigars and E-pipes are available. The following information is based on data regarding E-cigarettes. There are currently over 40 brands of E-cigs, in contrast to 5 major tobacco companies, worldwide and they all contain slightly different ingredients. None of these companies have publically disclosed 100% of their ingredients. E-cigs were first manufactured en masse in 2000; they are a Japanese concept from 1963 although the first patent was filed in the US.

- 20% of current smokers have tried E-cigs, only 7% are still using.
- 1/5 users has managed to quit smoking altogether (current NRT; 6.75-14.6%); difficult to compare e.g. Number of quit attempts etc.
- 4/5 (80%) e-cig smokers still smoke conventional cigarettes also.

All vape/e-cig systems consist of the same thing: Indicator light, battery, atomiser, cartridge (nicotine, propylene glycerol or glycerine and water, flavours, other).

In the UK any product that claims to treat nicotine addiction is considered medicinal and is subject to license according to MHRA; so companies do not make this claim and, currently, do not require MHRA license. They are not consumed so are not covered by the Food Standards Agency and are covered by general consumer protection law only.

Current UK use, approx. 1.3 million users (2013). They are not yet a recognised smoking cessation tool.

As for being safer; an electronic cigarette blew up in a Florida man's face, leaving him in a hospital with severe burns, missing his front teeth and a chunk of his tongue (CBS News). Tobacco regulation worldwide is strict, but E-cigs are classed as non-tobacco products.

CASE STUDY

TECC is a UK based e-cig company. Primarily sold on E-bay 2006. Turnover £1million/month (150,000 units/year).

Imported components, including vapour, from China. Now have a shop, in London, where consumers have free coffee and biscuits whilst trying the range of products. Primary marketing is via social media (unregulated). The company regards them as a consumer leisure product and does not think legislation is appropriate.

Viewed as a safer alternative as combustion and tobacco additives seen as the harmful parts of a cigarette.

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Source	Cons	Pros
British Medical Association	• Lack of evidence. • Undermine current efforts of smokefree legislation and makes cigarette smoking in work/ public places etc normal.	
European Commission	• Adverts banned due to unsubstantiated health claims. • Hungarian Survey; 13% 13-15 year olds experiment with e-cig.	
RAND Europe	• Lack of commercially available industry data. • PubMed; small body of data. • 80% water and glycerol – what's the other 20%? • Advertise as "harm reduction".	
ASH	• Little real world evidence; recent phenomena and lack of data.	• 48% smokers used in quit attempt, 31% of these reduced tobacco. • 32% of these quit tobacco
MHRA	• Variable delivery and nicotine levels. • Poor delivery systems.	• Satisfy hand-to-mouth (studies vs placebo)
WHO	• No evidence safe/effective. • Labelling is inconsistent and misleading.	• Does not exclude possibility that could be useful as smoking cessation aid.
FDA (US)	• Found carcinogen in toxic chemicals such as diethylene glycerol (1%) • Tobacco specific impurities in 50% of products. • Tobacco specific nitrosamine (carcinogenic in 50%) products.	

Dr Brendan Cooper, ARTP President, posted:

There is limited data on the acute effects of E-Cigs (I think we should move away from this term—"Vaping-sticks" may be better?). However, the studies are poorly designed and have the problems of differing chemicals/ derivatives, different delivery systems and limited physiological techniques to measure changes. Some studies (mainly abstracts) show a general pattern of an increased airways resistance and exhaled NO (similar to cigarettes), whilst others contradict this finding. There is little done on conventional lung function tests (we are submitting a research application on this). There is a need for some good physiological science to clarify whether we need to ask Vapers to refrain from smoking before lung function testing and determine what the acute effects of vaping is.

I am keen for the ARTP to have position statements and clear policy on relevant issues like this. However, as scientists we are not yet in a position to reach and scientific conclusions, so for now I believe the ARTP statement should read something like;

"ARTP realise the increased use of cigarette substitutes using vaping (or E-cigarettes) may be better than the knowingly noxious chemicals from conventional cigarettes, but to date there is no clear peer-reviewed, independent, published scientific evidence to conclude that vaping is safer than smoking. Rather than assume through ignorance that such vaping devices are completely safe, ARTP feel that research organisations should urgently fund some well-designed physiological studies on the short term effects of vaping to compliment the longer term studies on the pathological and epidemiological changes caused by vaping. Blindly accepting expert opinion that vaping is safe is unsatisfactory and may be exposing patients to risks that may have serious consequences in the years ahead. Until the evidence emerges that vaping is safe and reduces risk significantly, they should be given the same caution that cigarettes are given and should not be allowed to be used in public spaces and places"

It would be good to hear ARTP members comments on whether we should issue such a statement and what else we should say. Without the evidence, I don't think we should join the "Oh it must be safe" band-wagon! However, I don't think we should ignore the issue either.