December 2014

VOLUME 15, ISSUE 3

Inspire

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Inside this issue:

FIRST WORD 3

A WORD FROM THE CHAIR 4

THE PRESIDENT'S ADDRESS 6

ACADEMY OF HEALTHCARE SCIENCE INAUGURAL CONGRESS 8

A BASIC GUIDE TO CONTINUING PROFESSIONAL DEVELOPMENT (CPD) AND REGISTRATION BODIES 12

VARIATION IN QUALITY AND SAFETY PRACTICES IN RESPIRATORY PHYSIOLOGY LABORATORIES ACROSS THE UNITED KINGDOM: 16

GLI UPDATE 26

ON THE BLOWER 30

LUNG FUNCTION TESTING IN TRACHEOSTOMY AND LARYNGECTOMY PATIENTS—PART II 40

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FIRST WORD

1ST DECEMBER 2014
VOLUME 15, ISSUE 3

Hello again. Christmas greetings to you all! I hope you will be able to tear yourself away from festivities for just a few seconds to give this new Christmas Special edition your attention!

We start with motivational words from Chair and President, the latter reminding us of the human impact of what we do "*… how many patients have you comforted through their chronic disease? How many sleepy people improved on CPAP? How many people were given a clear diagnosis or perhaps had a bad diagnosis rejected?*", all easy to overlook as we rush through the daily routines of a busy department. Their report of the recent AHCS congress is also inside.

I recently attended the ARTP Strategy Day where a lively debate was had on the benefits of becoming registered as a Clinical Physiologist. One of the things that seemed to confuse many (including myself, before I attended, of course!) were the merits of the main authorities offering registration. I am pleased to say that as well as the link to the Strategy Day presentations we also have an article in this issue which provides a handy link to the ARTP official guide for those confused by it all.

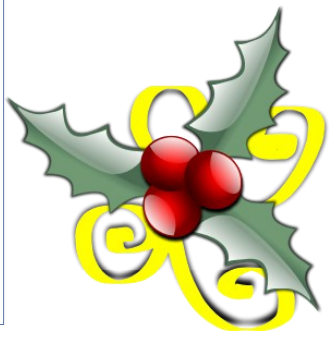
If you are lucky this Christmas, perhaps you will hear the sound of greetings cards tumbling through your letterbox (or maybe you are more of an email/ SMS type?!). You may also hear the thud of a dividend certificate if you are an investor in a PFT equipment provider, many of whom seem to be undergoing mergers. We are used to this type of thing in regular business but perhaps do not contemplate much in our PFT world. Once one thinks about the companies existing when we started in lung function, however, it is apparent that many have been subsumed into a much larger entity where possibly the personal touch has been lost. This is something which should concern us and 'On the Blower' in this issue makes this clear in describing recent 'Takeover Tales'. On the subject of 'OTB', Nigel Clayton announces in the column his decision to step down after 15 years as Chair of Manufacturers Liaison. I am sure you will join with me in thanking him for his service and also to welcome Stuart Wragg into the post.

There is an important survey looking into the degree of variability in Quality Standards across UK laboratories, which can impact significantly on patient care. Differing predicted values can impact on this also, of course and the GLI Implementation group publishes the results of it's recent survey in this issue.

Adrian Kendrick has delivered on his promise to provide Part II of 'lung function testing in tracheostomy and laryngectomy patients'. Only last week I was able to print part I and present it to my Consultant when she enquired about the feasibility of testing such a patient. Increased professional kudos duly followed—you have such articles at your fingertips as ARTP members!

I want to thank all contributors to this issue, including several 'new' authors who have provided articles or ideas over recent months. In response to feedback I have included PubMed reference links wherever possible, which should aid further reading. If you have suggestions for future articles in 'Inspire' or have written a piece for consideration please email me at: inspire@artp.org.uk or better still come and say hello and pass on your ideas in person at the ARTP Conference ARTP 2015 in January!

AIDAN LAVERTY



A WORD FROM THE CHAIR

Dr. Karl Sylvester

ARTP Honorary Chair

Welcome to another edition of Inspire and this edition's Chair's message. Since the last edition the days have started to draw in and the temperature started to drop but I'm sure the furnace of respiratory industry is keeping you all toasty.

Possibly the thought of another amazing conference is warming the cockles a tad too? A slight update to the last Chair's message with regards conference is the addition of some sessions we have labelled as "Junior Member Sessions". These are designed to give attendees some information of various basics of lung function testing. We've included measurement of gas transfer, interpretation of spirometry and different techniques for measuring lung volumes, so I hope you find these useful. Always happy to receive feedback, particularly sessions you'd like to see next time. Just to remind you 2016 will be our 40th Anniversary year so expect something a little bit special.

Work previously mentioned that has now begun in earnest is the implementation of e-portfolios for our examinations. After much deliberation, ensuring that ARTP finances are being spent appropriately, we've chosen a provider best suited to our needs. Training on the use of the system for those directly involved, when all is up and running, will begin in December. ARTP are already the leaders of respiratory and sleep training and education. Ensuring provision of evidence of competence via electronic means and online assessments will mean we continue to stay at the forefront of education delivery.

As you are all aware, our lung function guidelines are now over 20 years old and very much due an update. The ARTP guidelines review group have met, determined the contents of new guidelines and assigned experts in their field to work on producing the chapters required. I am hopeful that we will have a rough first draft of these guidelines ready for review by the next conference, but must be mindful of the workloads of those volunteering their services to this very important piece of work. The plan is to have the updated guidelines published in a peer-reviewed journal next year and I hope these will be a response to many queries from members regarding ARTP's stance on a number of lung function issues.

As ARTP Chair I am mindful that I and my committee colleagues are here to serve you the ARTP members and to this end we do listen to your

requests and, wherever possible and feasible, undertake the work necessary to deliver. With this in mind, our workforce committee took on the task of producing generic job descriptions which we hope will be useful to all respiratory and sleep departments around the country. These are available on the ARTP website for members to download and adapt as they see fit. Certain areas that we hope we can make national policy are the requirement to be registered, be this a statutory or voluntary register and to have written into job roles the requirement to have involvement in some capacity with the national professional body. Hopefully if this is written into job descriptions which are agreed by management and trusts this will free individuals to attend and work on behalf of ARTP as part of their job role without the need to take annual leave, as I understand some ARTP volunteers are required to do. Please wherever and whenever possible use these job descriptions when advertising for new members of your teams. If you have any feedback on these job descriptions then please do contact the workforce committee through the contact details on the website.

I'm afraid there are no pretty pictures for this edition of Chair's message. However, with conference in between this and the next issue, I'm sure some "interesting" pictorial evidence from the conference will be forthcoming.

Look forward to seeing you all in a month. Please register for conference as soon as you can. Until next time, feel free to contact me at chair@artp.org.uk.

Presidential Christmas Message

DR BRENDAN G COOPER

President, ARTP

Another year approaches midnight and we can look back and see what a difference we have made, personally and collectively, from the dawn of 2014 to the midday of summer and the dusk of Autumn. (I thought describing the seasons as a day captures how fast the years are flying…and I don't think it's personal!). All of you will have experienced unprecedented pressures on your time, efforts and workload, as the NHS bears the brunt of increased demands on healthcare from a variety of sources. Recent reforms, changing patient demographics, the impact of national enquiries and reports (e.g. Francis) have all added to the workloads we face.

Of course this comes against a background of a coalition government cutting back on public spending and giving you a pay freeze to thank for the extra efforts! (I'm sure health service staff will repay their gratitude in next year's general election, but Christmas isn't the time to be too political!). However, whatever conglomeration of political parties govern next time, don't expect any large increase in pay or decreases in workload, 2015 isn't going to be much easier, but at least vast changes like we've seen recently in the NHS is unlikely to happen in the next decade. Whilst it's not unreasonable to be realistic, we should also remember that we still work in the best National Health Service in the world, we can have brilliant professional careers alongside (generally!) excellent colleagues and we can go home at Christmas knowing we have actually improved peoples lives in the last 12 months.

Unfortunately, the media can only report the doom and gloom, but they have to, to sell stories. There have been some awful atrocities in the last year (and recently), but you have to take things in the round…how many patients have you comforted through their chronic disease? How many sleepy people improved on CPAP? How many people were given a clear diagnosis or perhaps had a bad diagnosis rejected? How much has research helped our understanding of diseases and their treatment. ARTP members are part of a fabulous team and you should be very proud to be a part of it within your organisation, your hospital and your busy departments. I feel immensely proud to be your President and don't hesitate to mention the great things that you all do to whoever wants to hear it! (Julie is sick of me going on about it at breakfast every day!)

Our Chair, Karl and I recently attended the first Academy of Health Care Science (AHCS) Conference at the Royal College of GPs in London with a

Presidential Christmas Message

brilliant programme, excellent speakers and some highly motivational presentations to an invited audience of Chairs and Presidents of professional bodies. You can read the full report in this issue.

We were delighted when Luke Sullivan from West Hertfordshire Hospital was awarded the best poster & presentation in the Physiological Sciences section. His paper, based on early findings, demonstrated that patients with OSA who undertook muscle strengthening exercises had a significant reduction in the severity of their OSA. He gave a clear honest and well prepared presentation to a lecture theatre of senior British Healthcare Scientists. He showed off respiratory and sleep physiology at its best and was a credit to ARTP. What pleases me most is that there is no shortage of young, well trained, caring and smart talent like him throughout ARTP members. Even more pleasing is the flow of STP students coming through the system. These are our future – but we will need more.

At AHCS, I was able to present a workshop on empowering Healthcare Scientists in a bid to get more representation of them on Boards, either as Executive Directors or Non-Executive Directors (NED), so that we can influence Boards and represent, promote and disseminate the enormous experience and contribution HCS can provide to healthcare leadership. This is a theme ARTP will be pursuing in the year ahead. Whilst working in the laboratory, continually producing high quality tests, therapies and great caring is important, the more senior Physiologists/Scientists must not avoid contributing to the local shaping of patient pathway design. Avoiding training your own STP students in respiratory/sleep and cardiology/vascular is not feasible unless we avoid a major workforce crisis five years down the road and see a "dumbing down" of our profession. ARTP will not let this happen and will support you to stop it happening.

Finally, I would like to thank and praise the amazing people who are on the ARTP Board, ARTP Council and ARTP Committees who all year have worked incredibly hard on your behalf, to make things happen for the profession. They will all get a mention at conference, but remember they do the same job as you, have their own families and problems and still give so much to make ours the best physiological professional body in the world! Raise that glass!

Meantime, have a great holiday over Christmas (accepting that some of you will be from different cultures and creeds), and in our tradition of New Year's resolutions, think what you can give to ARTP in 2015 and how you might rise to some of the challenges above.

My very best wishes to you all at this close of the year,

Brendan

Academy of Healthcare Science Inaugural Congress

Royal College of General Practitioners, London 8th-9th December 2014

We attended the inaugural Academy of Healthcare Science congress on 8th-9th December at the Royal College of General Practitioners in London. In the Academy's own words: *"The overarching theme of the Congress was 'Passionate for patients, passionate about science' celebrating the contribution of all healthcare scientists translating scientific research into clinical practice and delivering modern, technologically enabled healthcare. The Congress was an opportunity to showcase the contribution science makes to healthcare to stakeholders and partners – including patients – and point to where it has improved the quality of all people's lives."*

The congress started with a motivational and inspiring presentation from **Andy Reid**, an ex-serviceman who had sustained significant injuries during a tour of Afghanistan leaving him without both legs and only one arm. During his recovery he promised himself he would work as hard as he could so that he could walk down the aisle and marry his girlfriend. He duly fulfilled this dream and many more since. He puts his ability to live his life to the fullest down to the Healthcare Scientists that have developed the prostheses he wears and their continued drive and effort to continue to improve and develop new systems faster. He could not thank scientists enough for what they have done for him and urged us to not rest on our laurels but continue to develop and invent new, faster, more economic solutions for a range of healthcare specialities.

The congress then heard from four leading scientists with the developments they have been making in their respective disciplines. **Dr Val Davison** updated us on genomics in healthcare and how sequencing the genome has advanced diagnosis and aided in the ability to deliver the correct interventions for a number of diseases. This included information on a presentation delivered later on in the programme by **Professor Sian Ellard** from the Royal Devon & Exeter NHS Foundation Trust who identified different gene sequences in babies born with diabetes that meant the correct intervention could be administered instead of the standard insulin therapy. Certainly in one case this resulted in significant improvements in cognitive and behavioural ability that would not have been the case without this ground breaking research.

Dr Ronald MacKay, Director, Christie Medical Physics and Engineering then presented on the use of proton-beam therapy for the treatment of certain cancers. Currently UK residents need to travel abroad to receive this treatment but Dr MacKay is leading on the development of two brand new state of the art proton beam therapy centres in the UK. One in London and the other in Manchester.

Professor Paul White from Addenbrooke's Hospital in Cambridge presented details on the work he has been undertaking investigating the use of non-beating heart donors to heart transplantation. The demand for heart donors is ever increasing and this strategy of using non-beating hearts as potential donor organs is being investigated as one possible solution to plug the gap. So far the work looks promising and non-beating hearts, after specific interventions, work just as well as live organ

donation.

Dr Steven Wood, Clinical Scientist, Sheffield Teaching Hospitals NHS Foundation Trust gave us an insightful presentation into developments in the field of virtual medicine. The vision for this work includes taking a complete physiological snapshot of a presenting patient and having the ability to investigate every organ and system virtually without the need for invasive procedures. This is work that is already well underway within the private sector and Dr Wood warns us to be aware of this upcoming technology before we get left behind.

Dr Keith Ison, Head of Medical Physics, Guy's and St Thomas' NHS Foundation Trust then put forward his case for one voice in healthcare science. There are around 50 scientific specialities and Dr Ison's belief is that we should all get together with one clear voice to provide opinion and expertise to national issues and lobbying government, a belief at the heart of the Academy's vision.

We then had a session from a number of scientists who had submitted abstracts for this inaugural congress. Among them was our very own ARTP member **Luke Sullivan** who presented his work investigating the use of a respiratory muscle trainer on treatment of obstructive sleep apnoea.

The day concluded with a presentation from **Dr Veronique Sauret-Jackson**, Managing Director, Cavendish Imaging and Cavendish Implants who discussed the current uses of 3D printing, particularly during surgery. Examples included printed templates being used for cosmetic surgery ensuring symmetry of a patient's face and replacement of skull fragments. A 3D replica was also made of the vascularisation of conjoined twins' brain tissue. This allowed surgeons to practice and determine the best approach to separating the twins increasing the chances of success.

Overall the first day was a huge success and highlighted the exceptional, ground-breaking and inspiring work that is being undertaken by healthcare scientists. It also highlighted the impact the work of Healthcare Scientists has on the lives of patients and how grateful they are for the work that we do.

The conference dinner was a modest affair compared to ARTP Gala Dinners, but did have an awards ceremony both for leaders in healthcare science but also for the best poster/ presentation. We were delighted when **Luke Sullivan** from ARTP won the award for the best presentation in the Physiological Sciences section. His paper demonstrated that patients with OSA who undertook muscle strengthening exercises had a significant reduction in the severity of their OSA. He gave a clear, honest and well prepared presentation to a lecture theatre of senior British Healthcare Scientists. He showed off respiratory and sleep physiology at its best and was a credit to ARTP.

Unfortunately, the call for abstracts was very late, but next year, when the 2nd AHCS appears we would hope that many of the posters presented at January 2015 ARTP Conference would be equally likely to be eligible for prizes, but more importantly will show off the excellent research respiratory physiology undertakes. We are as good and probably better than the Life Sciences and Medical Physics branches of Healthcare Science when it comes to quality research.

The AHCS is a relatively new organisation and effectively replaces the Federation of Health Care Science but furthermore acts as the regulation and education organs of the Modernising Scientific Careers which has given a common platform in scientific training in Healthcare to all 70 specialisms practiced in the UK. One of the clear messages the Conference has established is that unless all Healthcare Scientists speak with "One Voice" – to government, the public, the media and other health organisations we will be ignored, disregarded and side-lined in all important changes happening in UK healthcare. At this time of enormous change, great uncertainty and continual increase in demand on healthcare, we need to be heard and heard very loud and clear where it matters.

Our own **Dr Brendan Cooper** presented workshops on empowering Healthcare Scientists in a bid to get more representation of Healthcare Scientists on Boards either as Executive Directors or Non-Executive Directors (NED) so that we can influence Boards and represent, promote and disseminate the enormous experience and contribution HCS can provide to healthcare leadership. This is a theme ARTP will be pursuing in the years ahead. Sitting in the laboratory, continually bashing out tests and therapies and avoiding contributing to the local shaping of patient pathway design is not an option. Avoiding training your own STP students in respiratory/ sleep and cardiology/vascular is not feasible unless we have a major workforce crisis five years down the road and see a "dumbing down" of our profession.

The closing session of the Conference was a powerful, personal and brilliant reflection of healthcare science from our Chief Scientific Officer, **Professor Sue Hill, OBE**, a past-chair of ARTP and ARTP Special Award winner, who described her upbringing, career and often lonely role as CSO transforming the training and profile of Healthcare Science in the UK (and beyond). There has never been a more influential, empowering or visionary Healthcare Science leader in the UK that has done so much for our reputation, profile and influence at the highest level in government.

It is likely that there will be another AHCS Conference next year and we would like to see the "best of" ARTP Conference posters submitted and presented. Whilst there is still uncertainty about future regulation and training posts, we should be supporting all organisations that promote Healthcare Science and our professions. As you can see this conference offers an excellent opportunity to demonstrate the importance of Healthcare Scientists – something ARTP has being doing for nearly 40 years.

Dr Brendan Cooper, President, ARTP

Dr Karl Sylvester, Chair, ARTP

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A Basic guide to Continuing Professional Development (CPD) and Registration Bodies

Sara McArthur. Edinburgh Royal Infirmary

As we all work in a constantly changing scientific and technical field the importance of keeping up to date with current best practice is essential. This ensures patients are provided with the best diagnostic and evidence-based services possible. An integral part of this continuing professional development (CPD) is setting appropriate and relevant goals, aiming for increased knowledge in certain areas and utilising this knowledge in a clinical setting. Due to increasing demands on departments and services, it has become harder to set aside time to devote to CPD. In addition, financial constraints including lack of funding and reduced staffing reduces the potential to attend conferences and other external learning opportunities. However, there are activities we all perform on a daily basis that can count towards a CPD portfolio and it is important to understand that if you are a member of any regulatory body then CPD is often mandatory in order for registrants to remain on the register. Individuals can be audited to see if they are complying with any of the registration body's CPD expectations

CPD is important whether or not you are a member of a registration body. It is important to stay clinically up to date, not only for a sense of personal achievement, but to uphold good clinical practice that benefits patients. If you struggle trying to find time for CPD then make sure that your line manager has a yearly review (which are mandatory) with you which incorporates the expectations of your knowledge and skills framework (KSF) and sets a personal development plan so you can work towards those goals set.

This brief guide has been developed to assist ARTP members in the development of their own CPD portfolio but there are many resources available which can be used for reference.

What can be included as evidence of CPD?

The following list is by no means exhaustive but does give ideas of what can be recorded and counted towards CPD.

- Attendance at Conferences, Lectures, Seminars or other meetings (e.g. regional groups)
- Webinars
- Mandatory NHS Training
- Undertaking or presenting research or audit
- Teaching, supervision and mentoring students in the workplace. You could also include healthcare professionals such as nurses, physiotherapists, medics etc.
- Lecturing, presenting or teaching including healthcare professionals such as nurses, physiotherapists, medics etc.
- Reading journals or articles or attending journal clubs
- Involvement in a regulatory or professional body work
- Reflective Practice

- Attending MDT meetings
- Attending ward rounds or outpatient clinics
- Writing papers, abstracts or poster presentations
- Development of resources (e.g. patient information leaflets)

Each registration body has guidance on what can be included which can be found on the website links at the end of the article. The ARTP also has a template which can be used as a CPD portfolio which can be found on the members' area of the website along with additional information .

How to record CPD?

The mainstay for maintaining a record of CPD is a lever arch file, with copies of attendance certificates or summaries of where, when and what were the learning outcomes. This works well and can be easily added to. However, many people find it easier to maintain an electronic copy of their CPD. The simplest form can be a table in Excel with attendance certificates scanned and linked to within the file. The advantages of this method are that it can be easily added to on the go and copies can be kept and accessed in multiple locations.

Registration bodies often have templates on their websites of layouts for recording CPD.

When do the registration bodies audit members CPD?

Each registration body has differing schedules for auditing CPD.

Registration Council for Clinical Physiologists (RCCP) - 5% of their membership are audited every 3 years. The next audit is due in April 2015 and covers CPD from March 2014 to April 2015.

The Academy for Healthcare Science (AHCS) - Their standards for CPD was published at the end of July 2014. Their audit will be of a random sample of members covering the previous 2 years CPD.

Association for Clinical Scientists (ACS)- On-going CPD to maintain the standards of HCPC registration.

Chartered Scientist (CSci) - Annual CPD monitoring.

Registered Scientist (RSci) - Not Specified but expected annual CPD.

With regard to registration bodies the ARTP does not dictate which body to become part of although employers often stipulate which one is required. The ARTP has put together a guide to help you try and decide—visit:

http://www.artp.org.uk/en/professional/confused-about-registration/index.cfm

Registration Body Guidelines and information on CPD can be found here:

- **RCCP:** http://www.rccp.co.uk/articles/86/Want-to-know-more-about-CPD
- **AHCS:** http://www.ahcs.ac.uk/wordpress/wp-content/uploads/2014/07/AHCS_StandardsOfCPD.pdf
- **RSci**: http://professionalregisters.org/whatisit
- **CSci:** http://www.charteredscientist.org/about-csci/cpd-standards
- **ACS:** http://www.assclinsci.org/acsHome.aspx

Should you have any further queries or comments then please feel free to email

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

Joao Correia – Imperial College Healthcare NHS Trust

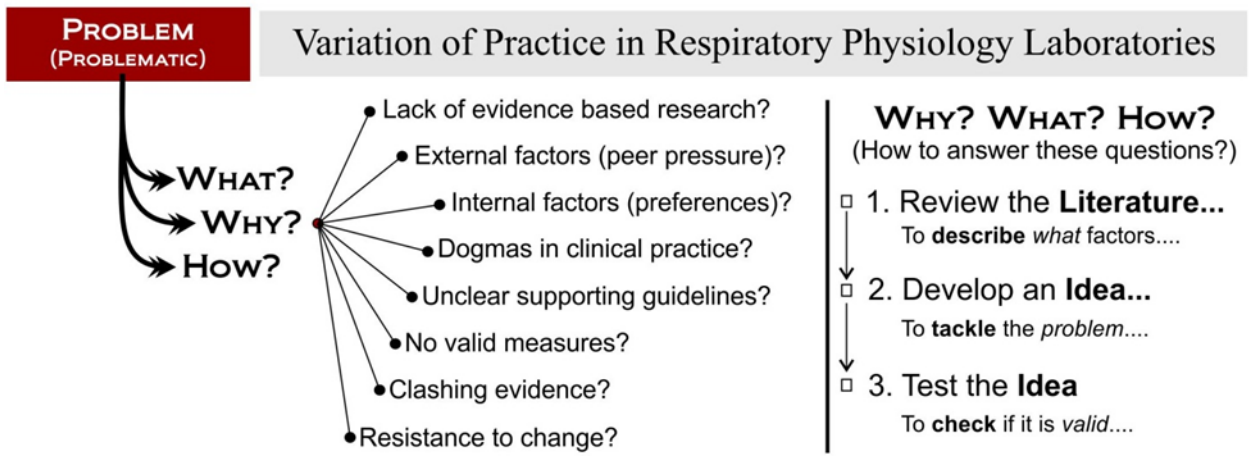
There is a wealth of evidence available in literature on how to perform safely and to a high standard an array of investigations commonly performed in Lung Function Laboratories. This evidence has produced solid guidance to all Healthcare Professionals working in this setting. In spite of this, it is not truly clear if such guidance is being followed and to what extent practice varies.

INTRODUCTION

The investigations performed in Respiratory Laboratories play a vital role in the diagnosis and follow-up of patients, not only with respiratory conditions, but also a series of other illnesses. The measurement and interpretation of these tests is not an easy task. To do it accurately, confidently and to an acceptable standard, is even harder. There are numerous physiological and non-physiological variables that can obscure the validity of the test results[1]. A comprehensive Quality Assurance (QA) programme with regular Quality Control (QC) measures is essential to minimise and contain sources of error[2]. The QA recommendations for Lung Function Laboratories[3] published by the ARTP in 2006 provide an overview of interventions that should be common practice in every laboratory across the United Kingdom (UK).

Ensuring a safe environment to patients is no less important. Risk management strategies are normally focused around infection control, contraindications to testing and effective management of unexpected incidents. The evidence -based research supporting such practices is limited and often grounded in experts' opinion. Although there is guidance available[4,5,6] local laboratories may have a different approach at tackling safety related concerns. Figure 1 illustrates a series of reasons why safety and quality related interventions may be susceptible to variation.

Figure 1 The problematic in study - What? Why? and How?



The context in which variation occurs has different repercussions. Variation between laboratories implies a small degree of comparability in the test outputs and is therefore a barrier to multicentre research studies. Variation within laboratories may have a significant impact in patient care, where significant changes in the variables being measured can be a result of varying testing procedures rather than actual changes in the clinical condition of the patient. It may be arguable however, whether standardisation has any value in clinical practice. A laboratory may well have rigid QC measures that are not necessarily in line with national

recommendations and still record valid and reliable measurements. Nevertheless, there is an overall agreement that varying practice can lead to inaccurate test results and potentially unsafe patient care[7]. In view of this, the present study aims to ascertain the degree of variation in Quality and Safety practices in Respiratory Laboratories across the UK.

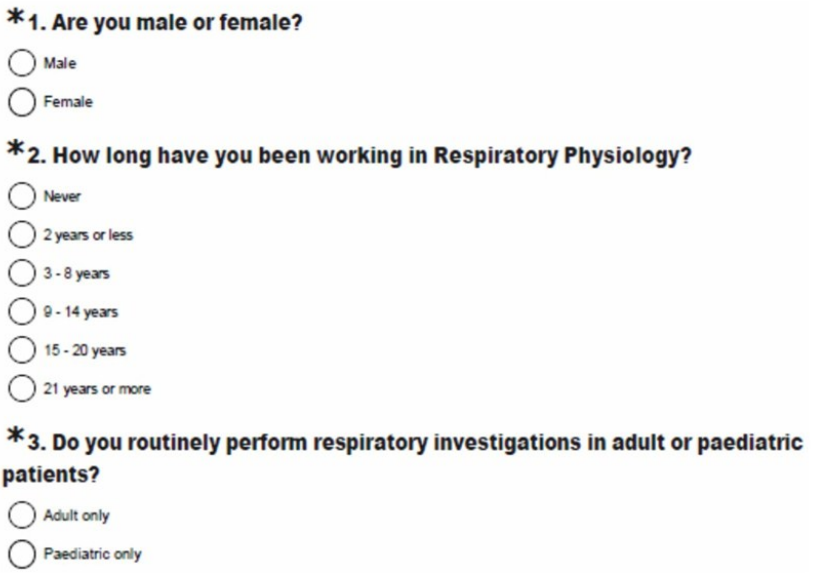
METHODS

A survey was designed using the online application SurveyMonkey® to perceive the degree of variation in quality and safety practices, identify barriers to good performance in a Respiratory Laboratory and determine if physiologists receive regular feedback.

The ARTP and the recruitment agency Your World® agreed to distribute the survey via e-mail. A set of instructions was given to ARTP and YourWorld® to systematise the data collection process. Data collection was planned to last approximately 1 month. During this time frame weekly reminders were sent to the respondents to maximise the number of submissions. To ensure an appropriate response rate, decrease the likelihood of social desirability bias and abiding to ethical recommendations, the IP address of respondents was not stored, to preserve anonymity.

The survey used to collect the data has a total of 10 questions distributed over 4 pages. The first page, entitled "Data Descriptors", was used to characterise variables that might impact on the following sections of the survey. Gender is a common subject in questionnaires. Question 1 is used purely for demographics. The ratio of male to female respondents may be useful to cross check the representativeness of the sample with the ARTP survey published in 2012[8]. Experience may have a significant impact in the perception of quality and safety routines. One would also expect that those who have the most experience in respiratory physiology are more likely to have managerial responsibilities, and therefore better perception of factors that affect performance. If respondents indicate that they have never worked in respiratory physiology the interface automatically directs the participant to the disqualification page. Question 2 addresses this by asking about years of experience (tenure). Respiratory Physiologists perform investigations in adults and children. It would be important to understand if there are any significant differences on the importance of the patient, as a specific factor, in recording valid and reliable measurements. Question 3 divides the sample in to 2 groups, those who perform tests in children and in adults. Figure 2 shows the first survey page and the initial questions aforementioned above.

Figure 2 QASI Survey Page 1 - Data Descriptors



The second page, titled "Your Practice", aims to perceive the degree of variation in quality and safety practices. Question number 4 has a total of 8 items. In 2006 the ARTP published standards and recommendations for quality assurance practices in respiratory laboratories[3]. Items 2 to 7 are a reflection of the recommendations from the ARTP. Pretto and colleagues found that the majority of the workload in respiratory laboratories is to monitor disease progression and determine responses to treatment[9]. Item number 1 aims to determine whether this is the case in the UK setting. If most respondents consider the statement as being true it would be important to see if there is a different approach in the way longitudinal measurements are performed, it also heightens the importance of performing regular Biological Quality controls instead of isolated physical calibrations. Several authors claim that the healthcare professional conducting the test is the most important intervenient in any Laboratory[10,11]. Further emphasis in learning opportunities and the importance of feedback is also given in literature[4]. The last item in question 4 aims to establish if physiologists receive regular feedback. The purpose of Question 5 is for respondents to identify factors in their work environment that have a negative impact on performance. Free text entry was added to question 5 to give the respondents the possibility of adding other factors that were not listed. Content analysis was used to explore further themes and views "hidden" in the free text. Figure 3 shows the second survey page and the questions concerning variation in quality and safety practices.

Figure 3 QASI Survey Page 2 - Your Practice

***4. Considering your own practice, please select true or false for each of the following:**

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

***5. What are the main factors that have a negative impact in the performance of your department? (please select 1 or more options)**

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

Other (please specify)

The remaining 5 questions distributed over the last 2 survey pages were used to capture the perceptions of Respiratory Physiologists/Scientists about Quality, Safety and Performance in Lung Function Laboratories. This data will not be presented here, but will be compiled with a systematic review of literature in an attempt to develop a framework to support Physiologists.

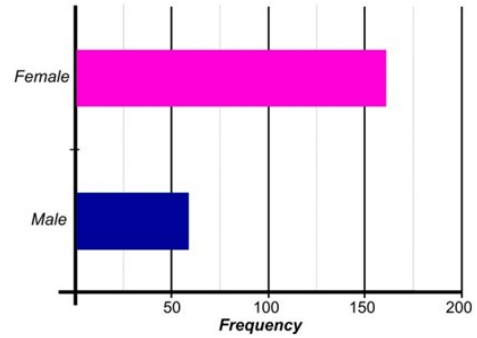
RESULTS

The data collected from the survey started on 31/07/2014 and was finalized on 29/08/2014. A total of 221 submissions were recorded (25% response rate - estimate). Data analysis was performed with statistics software IBM SPSS® (SPSS 22.0, SPSS Chicago, Illinois).

Figure 4 displays bar charts and frequencies of the observed sample. The number of female respondents was considerably higher. Only 26.8% respondents were male. These findings replicate similar gender ratios when compared to the surveys conducted by the ARTP in 2005[12] and 2012[8]. The 6 different classes used to determine the experience of physiologists were not equally represented. One of the respondents had no experience in respiratory physiology and was eliminated from the pool of responses. More experienced physiologists (>9 years) account for 64.5% of the total number of responses. A minority (9.1%) of the respondents perform investigations in children. This is likely to be a reflection of the few specialist paediatric services in the UK.

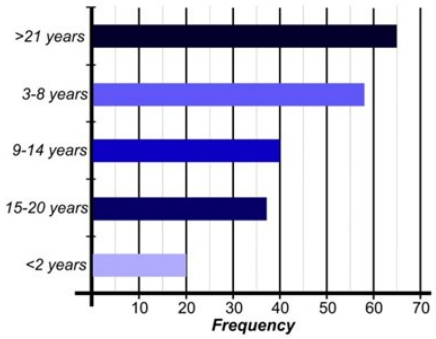
Figure 4 Observed sample descriptives (Q1, Q2 and Q3)

Q1 - GENDER



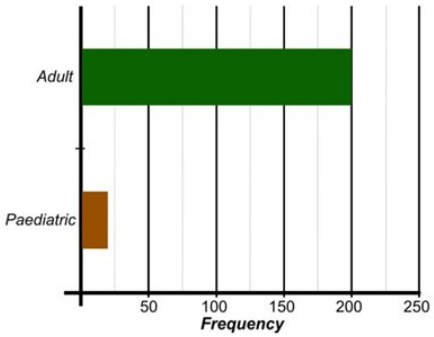
	frequency (f)	percentage (%)	valid %	cumulat %
Female	161	73.2	73.2	73.2
Male	59	26.8	26.8	100
Total	220	100	100	

Q2 - TENURE



	frequency (f)	percentage (%)	valid %	cumulat %
>21 years	65	29.5	29.5	29.5
15-20 years	37	16.8	16.8	46.3
9-14 years	40	18.2	18.2	64.5
3-8 years	58	26.4	26.4	90.9
<2 years	20	9.1	9.1	100
Total	220	100	100	

Q3 - TESTING SUBJECT



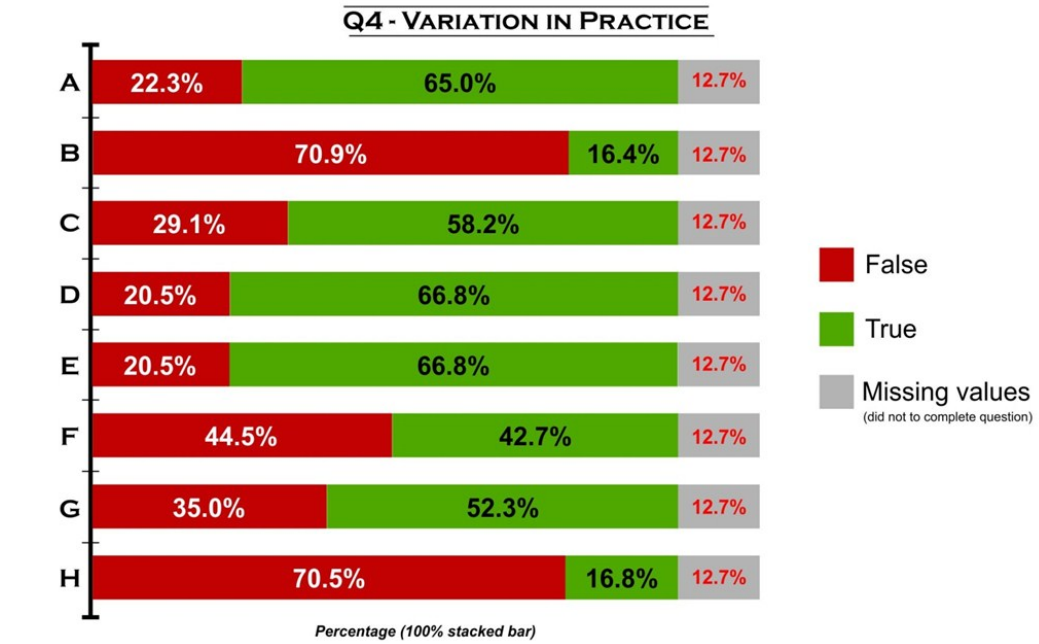
	frequency (f)	percentage (%)	valid %	cumulat %
Adult	200	90.9	90.9	90.9
Paediatric	20	9.1	9.1	100
Total	220	100	100	

Figure 5 graphically exhibits, using stacked bars, the degree of variation in quality and safety practices. Only 16.8% of the respondents receive regular feedback. 65% affirm performing more commonly tests to monitor disease progression.

Items B to G aim to portray the degree of variation in practices that play a role in quality and safety within a Lung Function Laboratory. 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 equipment, this seems to occur more frequently in comparison to biological quality control, which is known to be a crucial part of QA programmes. Lastly, 70.9% of physiologists negate receiving referrals completed in full.

The information recorded in question 4 suggests that variation in quality and safety practices exists. The most striking finding is the fact only a minority of physiologists receive regular feedback. It may be important to note that the majority of respondents have been working for more than 9 years in respiratory physiology. It is unclear if this can contribute to such a small percentage of physiologists receiving regular feedback. Another alarming finding is the few respondents that report receiving referral forms completed in full. This has implications in the scheduling of patients, appropriate interpretation of test results and risk surrounding cross-infection in patients who may be immune-compromised. Unexpectedly, despite the emphasis given to biological quality control in literature, only 42.7% affirm they are given the time to regularly perform biological calibrations. In an attempt to perceive if there are any factors that could explain the degree of variation in practice, respondents were also asked about factors that may have a negative impact in the performance of a Lung Function laboratory.

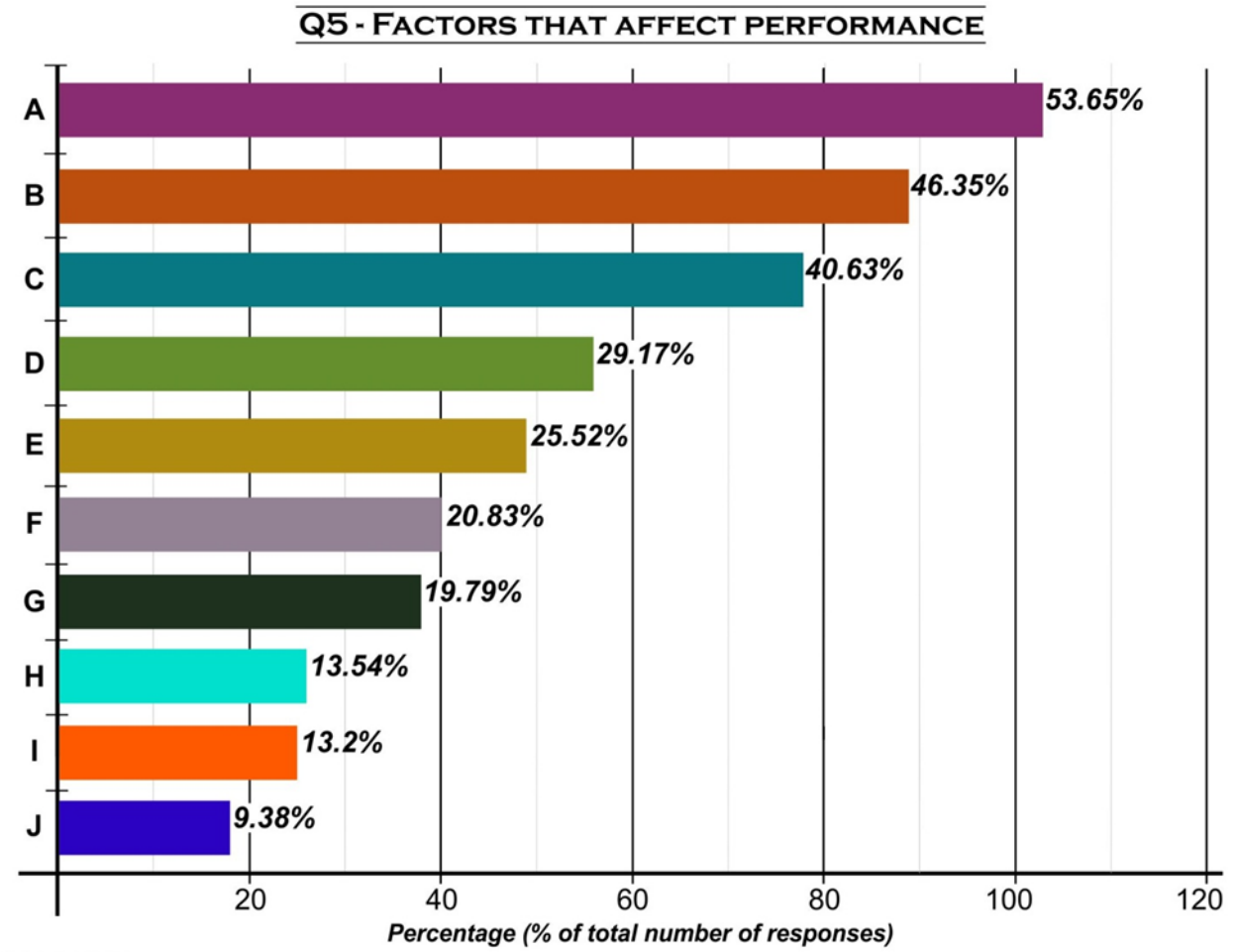
Figure 5 Graphical representation of the degree of variation in practice (Q4)



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

Figure 6 Graphical representation of factors that have a negative impact in performance (Q5)



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

Figure 6 lists the different sentences used in the survey to grasp what could be the most common issues limiting the performance. More than 50% of respondents consider their department understaffed. The fact that 46.35% of the physiologists report funding restrictions is likely to explain that short-handed departments may not be a consequence 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 any factors that may negatively affect their practice performance.

The free text data entry recorded 15 submissions (Figure 7). There are a few repeated themes, including understaffing, no administrative support, poor management (Cardiology) and "detachment" of Respiratory Consultants from the Respiratory laboratory problems. Other themes have emerged, for example: job satisfaction (working alone), the physical characteristics of the clinical environment and clinical governance matters (patient safety, privacy and dignity).

Different types of bias may have blurred the data collected. The first and perhaps most important source of noise was the use of convenience sampling. As a result, the external validity of the findings is uncertain. Conversely, the members of

the ARTP represent a core part of the physiologists working across the UK. In the same line of thought, the participants that voluntarily decided to complete the survey might have done so as a result of frustration for not being able to implement the necessary changes to improve standards at a local level. As a result, this participation bias may have contributed to an overestimation of the degree of variation in quality and safety practices reported in this study.

Figure 7 Free-text entry of additional factors that have a negative impact in performance (Q5)

Q5 - FACTORS THAT AFFECT PERFORMANCE (FREE-TEXT ENTRY)

Entry	Free-Text
1	Ever increasing demand on services with a lag in resources to provide a higher level of service
2	Poor clinical environment
3	Testing space is very limited. Only have 1 large room
4	SLA with PFI building
5	Extra consultant clinics but our staff not taken into account
6	Cardiorespiratory/sleep dept - Cardiology dominates
7	I work alone and there is no cover for me when I am on annual leave or have to take sick leave and I have limited administrative support. So when I return I am faced with a back log of referrals to book appointments for etc.
8	I work alone in a private practice
9	Respiratory physicians do not have an interest in the lab, but quick to complain
10	Very limited space for working
11	patient privacy and dignity,
12	Large demand for services from across the hospital. Respiratory Consultants believing that we only see their patients where as we actually see a large number of non-respiratory patients.
13	No time allocated for Quality Control/ PDP/cleaning etc-just have to fit in between patients
14	Unqualified staff permitted to perform tests
15	Lead physiologist is a cardiac manager who shows little interest in the lung function lab development

FURTHER RESEARCH AND RECOMMENDATIONS

The information recorded from the survey has provided only a snapshot of the degree of variation and the current problems Physiologists/Scientists are faced with. The anonymity of the survey did not allow the recording of variables that may be fundamental to further understand and tackle variation in practice, for example departmental size and scope of practice (single area or multidisciplinary). A qualitative research design would provide a much better picture of the various issues that affect performance. The information recorded from interviews or focus groups would be more "soft" in nature, allowing, in theory, to perceive what are the root causes for the problems identified in the study. Another interesting path of research, in view of the poor job retention rates across the National Health Service (NHS), would be to comprehend what factors are associated with higher job satisfaction among Respiratory Physiologists/Scientists. There is also an obvious need for research aimed at addressing knowledge gaps in an era of evidence based medicine. Local and regional research (including small scale audits) is vital to discover and critically evaluate the confounding factors surrounding a clinical environment, which controlled trials are not able to

account for. The counter argument to this is that much larger scale research is needed to produce the levels of evidence that ultimately can modulate clinical practice. First though, we need to minimize the degree of variation between Respiratory Laboratories across the UK. Figure 8 lists a few recommendations based on the information recorded from the survey.

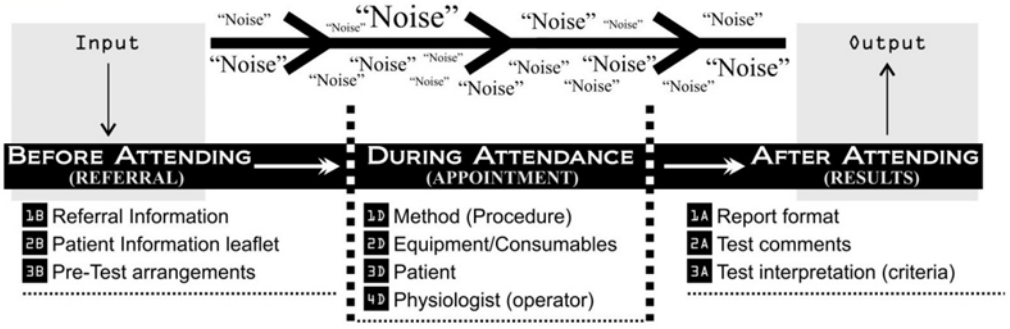
Figure 8 Unifying practice in Respiratory Physiology across the UK - Recommendations

1 GUIDELINES/RECOMMENDATIONS UPDATE - IS IT REALLY GOING TO MAKE A DIFFERENCE?

Most of us know that the BTS/ARTP guidelines published in 1994 need to be updated. The latest recommendations published by the European Respiratory Society and American Thoracic Society Taskforce (ERS/ATS) in 2005 represent a gigantic step in the Standardisation of lung function tests. In equal terms the set of reference data published by the Global Lung Initiative (GLI) is also a major contribution.

In hindsight, we should know by now that guidelines are not practical. The series of documents published by the ATS/ERS Taskforce have in total 57 pages. Would another 20-30 page document help to standardise practice?
In addition to this, there is often a varied group of investigations, each with a specific set of guidelines. The ever growing complexity of Respiratory Laboratories and expanding roles and responsibilities of respiratory physiologists/scientists urges a different approach.

SUGGESTION — Framework reviews (organize information logically) of the different testing modalities with supporting documentation in annexe (patient information leaflets, procedural guidance, etc...)



Adapted from MSc Thesis entitled "Development and validation of a Framework for Quality and Safety Indicators (QASI) in Respiratory Physiology (2014)

Figure 8 (continued) Unifying practice in Respiratory Physiology across the UK - Recommendations

2 QUALITY ASSURANCE (QC AND FEEDBACK) - NEGATIVE FEEDBACK IS BETTER THAN NO FEEDBACK AT ALL

Less than half of the respondents reported not having scheduled time to perform Biological Quality Controls. Taking into account that the majority of the workload of Respiratory Labs is to monitor disease progression it is of the utmost importance to check regularly the stability of the measuring equipment. Surely, Respiratory Consultants understand the potential implications in patient care if systematic measuring errors occur.

Feedback and learning from own practice is a key part of the development of respiratory physiologists/scientists. Only a minority of the respondents reported receiving regular feedback (monthly basis). Once again Respiratory Consultants or more senior scientists should play an active role in the delivery of feedback, formally or informally.

SUGGESTION — The medical director (US term) plays a key role in the Quality Assurance of a Respiratory Laboratories. In the UK having a medical doctor in a similar role could help to raise concerns to senior management and work together to create the conditions necessary to perform measurements at an acceptable standard

3 INFECTION CONTROL - BETTER SAFE THAN SORRY

The test referral is often the only information available when scheduling patients and organizing clinic lists. The majority of the respondents reported receiving referrals not completed in full. From an Infection Control point of view, can we rely on the referral information? I guess most of us would say no...

SUGGESTION — This is not new, but it seems that it is better to be safe than sorry (every patient is potentially infectious) in comparison to the evidence based approach (no evidence suggesting cross-infection). Regular disinfection procedures, together with the use bacterial filters are a must.

FINAL CONSIDERATIONS

In summary, variation in quality and safety practices exists across the UK. Poor communication between senior management and operational level work seems to be a key determinant to varying practice. Additionally, only a small fraction of respiratory physiologists receive regular feedback.

ACKNOWLEDGEMENTS

A sign of appreciation to the members of the ARTP research group, Dr Roger Carter, Dr Catherine Billings, Dr Karl Sylvester and Dr Brendan Cooper for the comments given in the initial phases of the project and for taking the time to review the pilot version of the online survey. The distribution of the survey to the ARTP membership would have not been possible without the help of Phil Baker. I am grateful for his availability and the professionalism he demonstrated in the distribution of the survey. Luke Dyer kindly offered is help to distribute the survey to locum physiologists registered with Your World Recruitment®. I also thank him for the availability and support.

REFERENCES

1. Crapo, R. O. & Jensen, R. L. (2003) Standards and interpretive issues in lung function testing. Respiratory Care. 48 (8), 764-772
2. Cramer, D., Ward, S., Unstead, M., Ming, J., Thomas, S. & Wells, A. (2011) Biological quality control data relating to lung function and cardioplumonary exercise. Inspire. 2 (11) - ARTP MEMBERS ONLY
3. Butterfield, A. K. (2006) Quality Assurance for Lung Function Laboratories—ARTP MEMBERS ONLY
4. Miller MR. Crapo R. Hankinson J. Brusasco V. Burgos F. Casaburi R. Coates A. Enright P. van der Grinten CP. Gustafsson P. Jensen R. Johnson DC. MacIntyre N. McKay R. Navajas D. Pedersen OF. Pellegrino R. Viegi G. Wanger J. ATS/ERS Task Force. (2005a) General considerations for lung function testing. European Respiratory Journal. 26 (1), 153-161
5. Kendrick, A. H., Johns, D. P. & Leeming, J. P. (2003) Infection control of lung function equipment: a practical approach. Respiratory Medicine. 97, 1163-1179
6. Cooper, B. G. (2011) An update on contraindications for lung function testing. Thorax. [Online] 66 (8), 714-723.
7. Laszlo, G. (1984) Standardised lung function testing. Thorax. 39, 881-886
8. Butterfield, A. K., Cooper, B. G., Bucknall, M., & Sylvester, K. (2014) ARTP 2012 Survey of Respiratory & Sleep Services. Association for Respiratory Technology and Physiology (ARTP) - ARTP MEMBERS ONLY
9. Pretto, J. J., Brazzale, D. J., Guy, P. A., Goudge, R. J. & Hensley, M. J. (2013) Reasons for Referral for Pulmonary Function Testing: An Audit of 4 Adult Lung Function Laboratories. Respiratory Care. 58 (3), 507-510
10. Enright, P. L., Beck, K. C. & Sherrill, D. L. (2004) Repeatability of Spirometry in 18,000 Adults. American Journal of Respiratory and Critical Care Medicine. 169, 235-238
11. Haynes, J. M. (2012) Quality Assurance of the Pulmonary Function Technologist. Respiratory Care. 57 (1), 114-122
12. Butterfield, A. K. (2006) ARTP Survey 2005. Inspire - ARTP MEMBERS ONLY

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GLI update

Dr Jane Kirkby, Lead of GLI implementation group

In September 2013 the ARTP officially endorsed the Global Lung Function Initiative (GLI) spirometry reference equations for use in the UK, and implementing GLI was an ARTP primary objective in January 2014. This article summarises the key points discussed in the recent National Strategy Meeting in October 2014.

What was the Global Lung Function Initiative (GLI)?

The GLI network comprised 234 registered individuals (clinicians, researchers, technicians, IT engineers, and manufacturers) from 41 countries across 5 continents. During the data collection period they collated over 150,000 spirometry data points. After extensive data cleaning and exclusions (e.g. due to missing ethnic groups or suboptimal quality control) and use of advanced statistical techniques (the LMS method (lambda-mu-sigma) that allows the development of smoothed curves and efficient calculation of *z* scores simultaneously) the first all-age, global multi-ethnic reference equations for spirometry based on ~74,000 healthy non-smoking subjects aged 3-95 years was published in the *European Respiratory Journal* [1]

Why should we use GLI reference equations?

The principles behind normative reference data are based upon the theory that a summary measure of values obtained from "normal" individuals will represent the range of values expected in a healthy population. A literature search on *Pubmed* will reveal over 300 spirometry reference equations relating to all sorts of differing populations, age-groups and nationalities [2], hence it can be challenging to decide which one to apply. Although there are published, evidence-based recommendations on equipment specifications, spirometry performance and identification on technical acceptability [3-5], it is largely the user's responsibility to select the most appropriate reference equation for their population. Until last year (2013) the ARTP recommended the *European Coal and Steel Community (ECSC)* equations for adults [6] and Rosenthal for children [7]. How appropriate were these recommendations?

The ECSC was the first organisation to issue recommendations for spirometry in 1960, and issued predicted values in 1971. Rapid technological developments lead to a revision of the ECSC report in 1983 (this included lung volumes), and further updates in 1987 (to include TL_{CO}), 1993 and 1994. Hence the recommendations were combined sets of reference values across several decades. Furthermore, the sets of reference values issued by the ECSC were based on Caucasian males aged 18-75 years working in coal mines and steel works, and although no women were tested, the ECSC issued reference values for females (80% of the values for males). Thus the ECSC is not representative of the population we measure today. In paediatrics, the "Brompred" Rosenthal reference equations were based on 772 (455 male) Caucasian children aged 4-19 years. It included pubertal assessments (Tanner assessments developed in 1962) to adjust for varying thoracic dimensions during puberty, however pubertal assessments are rarely measured in the clinical paediatric lung function laboratory, resulting in arbitrary break points for puberty and further changes during transition to adult care. Finally the use of traditional linear regression equations to develop the ECSC and Rosenthal reference equations was limited since the relationship between lung function, age and body size is not

linear. Use of advanced statistical techniques such as the LMS method is essential when adjusting for the complexities of the determinants of lung function (age, height sex and ethnicity).

The publication of the new GLI All-age, multi-ethnic reference equations have overcome many of the limitations previously experienced. Philip Quanjer, the lead author for the ECSC has worked tirelessly in his retirement to update his reference equations. On a recent discussion with him he stated: ***"We have known for years that these (ECSC equations) are wanting, and they are now superseded by the GLI-2012 equations which have been shown in a number of studies to fit various populations, cover a very large age range, can be applied to a number of ethnic groups."*** The ARTP now recommend the use of GLI spirometry reference equations.

Is GLI being used?

GLI is being used extensively in research. At the recent ERS conference in September there was one oral presentation session led by group 9.1 (Respiratory Function Technologists/ Scientists) entitled "The impact of the Global Lung Initiative (GLI) reference equations and spirometry quality in all ages" and over 50 poster presentations with GLI as a key word. Increasingly editors of respiratory journals request results to be presented as GLI as it is more applicable to a wider audience, however implementing into research practice may be easier than implementing into clinical practice. The recent ARTP survey (Figure 1) revealed some of the anxieties about changing reference equations. Whilst we are working with the manufacturers to ensure a smooth (and cheap) transition to GLI, the apprehension to change because the clinical team won't support it, or concerns about the mixed reference equations were issues that needed urgent attention, and we hope that with further education and information you can demonstrate to the clinical team that changes are required.

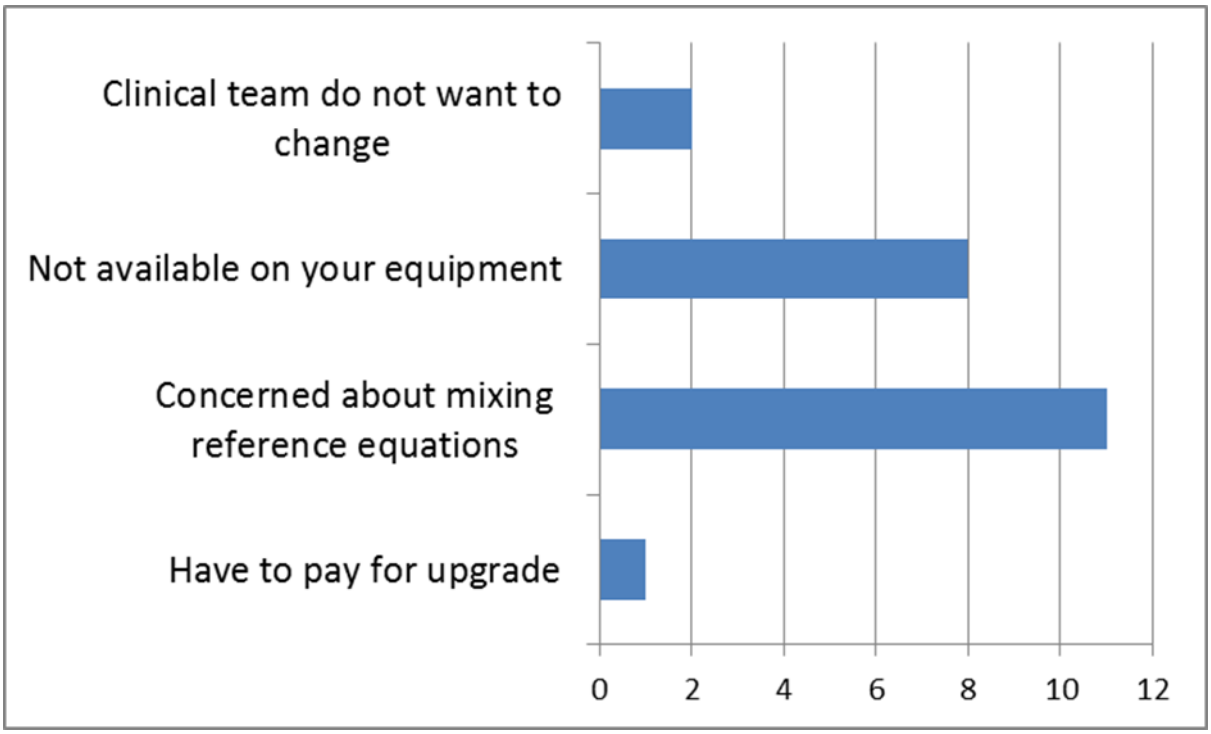


Figure 1: Results from ARTP survey: Common anxieties to changing reference equations

How do we mix reference equations on the reports?

There is concern that since the GLI equations are only available for spirometry the mixed reference module (ECSC for lung volumes and TL_{CO}) will be confusing with some people suggesting they will wait until new equations are available for all outcomes before changing. This approach is not feasible. The outcomes and inclusion criteria included in new reference equations are usually at the discretion of the investigators and very few will measure multiple outcomes, hence it is unrealistic to expect a single reference equation which encompasses everything to appear. Even the ECSC equations are a combination of various studies (TL_{CO} was not included on the original ECSC dataset), hence the way forward is working with the manufacturers to develop appropriate "prediction modules" which represents the appropriate reference equation for each outcome (as is the case currently). The possible discrepancy for predicted VC across TL_{CO} and spirometry can be overcome if VC is shown as an absolute number with no accompanying predicted value for TL_{CO} or lung volumes, and predicted FVC is only displayed with spirometry outcomes (as seen in Figure 2).

"The interpretation of discordant results (i.e. VC in normal range in GLI and outside normal range in ECSC) requires careful clinical judgement, rather than inappropriate application of out-dated reference equations." (P.Quanjer 2014).

		Best	% Predicted	Pred LL	Pred UL	Z-Score
FEV1	[L]	3.48	94	2.96	4.42	-0.50
FVC	[L]	4.11	96	3.47	5.08	-0.32
FEV1%F	[%]	84.59	97	75.43	96.43	-0.37
PEF	[L/s]	8.80				
MMEF	[L/s]	3.25	77	2.79	5.90	-1.06
Hb	[g(Hb)/100mL]	14.60				
DLCO_SB	[mmol/(min*kPa)]	8.99	106	6.51	11.07	0.32
VA_SB	[L]	4.57	92	3.89	6.37	-0.62
KCO_SB	[mmol/(min*kPa*L)]	1.97	108	1.42	2.23	0.58
DLCOcSB	[mmol/(min*kPa)]	8.99	106	6.51	11.07	0.32
KCOc_SB	[mmol/(min*kPa*L)]	1.97	108	1.42	2.23	0.58
VIN_SB	[L]	3.74				

* Please note the reference module changed on 29/04/2014. New predicted equations: Spirometry (3-95y)= GLI 2012 (Quanjer, ERJ 2012).
Gas Transfer =>19y Kim et al (Ped Pulm 2012); >19y = ECCS. Lung Volumes >19y Rosenthal et al (1993, Thorax), >19y = ECCS.
NB: Gas transfer and lung volume equations are based on white subjects and not corrected for ethnicity.
Percentage predicted values may vary when compared with earlier lung function test. For any additional information please contact the Lung Function Lab on extn: 5456

Figure 2: Example of a report which has mixed reference equations (GLI for spirometry and ECSC for TL_{CO}). Note that VIN is reported as a quality control check for TL_{CO} technique and the predicted columns are empty

Will it impact some patient populations more than others?

Yes. Slight differences in predicted values will occur in patient groups which were poorly represented in previous recommended reference equations:

- Children (particularly early childhood and puberty)
- Transition (at 18 year switch from paediatric reference data to adult reference data (and assumed to be 25))
- Adult women (not included in original ECSC data)
- Elderly: ECSC is extrapolated at 75yrs
- Non-Caucasian subjects: Ethnic differences previously estimated 10-15%.

CONCLUSION

Previously recommended equations have been shown to be outdated. Both the lead author of the ECSC equations and all international professional respiratory bodies have now recommended the use of GLI reference equations. We are doing our patients a dis-service if we knowingly apply inappropriate reference equations, and must now make a concerted effort to ensure we apply the most appropriate techniques for interpreting spirometry.

REFERENCES

1. Quanjer PH, Stanojevic S, Cole TJ, Baur X, Hall GL, Culver BH, et al. Multi-ethnic reference values for spirometry for the 3-95-yr age range: the global lung function 2012 equations. Eur Respir J. 2012;40(6):1324-43.
2. Stanojevic S, Wade A, Stocks J. Reference values for lung function: past, present and future. Eur Respir J. 2010;36(1):12-9.
3. Pellegrino R, Viegi G, Brusasco V, Crapo RO, Burgos F, Casaburi R, et al. Interpretative strategies for lung function tests. Eur Respir J. 2005;26(5):948-68.
4. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, et al. Standardisation of spirometry. Eur Respir J. 2005;26(2):319-38.
5. Beydon N, Amsallem F, Bellet M, Boule M, Chaussain M, Denjean A, et al. Pulmonary function tests in preschool children with cystic fibrosis. Am J Respir Crit Care Med. 2002;166(8):1099-104.
6. Quanjer PH, Tammeling GJ, Cotes JE, Pedersen OF, Peslin R, Yernault JC. [Lung volumes and forced ventilatory flows. Work Group on Standardization of Respiratory Function Tests. European Community for Coal and Steel. Official position of the European Respiratory Society]. Revue des maladies respiratoires. 1994;11 Suppl 3:5-40.
7. Rosenthal M, Bain SH, Cramer D, Helms P, Denison D, Bush A, et al. Lung function in white children aged 4 to 19 years: I--Spirometry. Thorax. 1993;48(8):794-802.

Nigel Clayton
Brendan Cooper-
Alan Moore
Stuart Wragg

ON THE BLOWER

In another bumper edition of "On the Blower" we have the latest on takeovers and acquisitions, lawsuits and management buyouts. If that's not enough to get your juices flowing we also have the ERS manufacturers awards for innovation together with the usual round up of company news and latest products.

Before we get to the juicy section, some of you may have noticed in the heading that we have a new addition to the manufacturers liaison committee. I have decided after more than 15 years acting as Chair of Manufacturers Liaison, to stand down and hand over the reins to someone with the time and enthusiasm to move manufacturers liaison to a new level. Stuart Wragg will be taking over as Chair of Manufacturers Liaison following the 2015 conference.

Throughout my 15 year tenure I have thoroughly enjoyed working alongside Brendan and Alan and have met many colourful characters within the manufacturing and sales industry. I have seen the development and implementation of many new products, particularly in the sleep industry. I have also seen the demise of companies where big investments have not paid off. Takeovers and acquisitions have also proliferated in this period, none more so than in 2014 as you will read below.

To introduce Stuart, he has worked in Respiratory Physiology for many years and now manages the Laboratory at Aintree University Hospitals, Merseyside. I wish Stuart all the best as Chair of Manufacturers liaison.

NC

NOTES TO MANUFACTURERS

To all the manufacturers who may be reading this article, please remember to keep us posted with details of any new products and company announcements. Details should be sent to Stuart.wragg@aintree.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.

More Sales than DFS

Readers may be aware of the regular round of "takeovers, mergers, sales and changes of name" that goes on with manufacturers of lung function equipment globally. Many names have come and gone. More senior ARTP members will recall the names of "Gould", "P K Morgan"and "Ohio" equipment, that have disappeared into the archive /museum of lung function. As an example of name changes let's look at the recent history of Carefusion. The history goes something like this:

1990s	*SensorMedics purchased by Thermo-Electron*
1999	*Erich Jaeger purchased by Thermo-Electron*
2001	*Thermo-Electron spins off its Respiratory Technology, Neuro-Care, and Medical and Surgical Divisions to form Viasys Healthcare*
2005	*Viasys buys MicroMedical, one of the largest vendors of spirometers in the world for $39 million*
2007	*Viasys Healthcare is acquired by Cardinal Health for $1.5 billion*
2009	*Cardinal Health, which already owned the brand name, splits off its clinical and medical products into CareFusion*

October 2014 – Becton Dickinson announces that it is in the process of purchasing CareFusion for the princely sum of $12.2 billion. The statement issued by the two companies to the stock exchange (and therefore potential investors) suggests what the company will concentrate on:

"The combination of the two companies' complementary product portfolios will offer integrated medication management solutions and smart devices, from drug preparation in the pharmacy, to dispensing on the hospital floor, administration to the patient, and subsequent monitoring. The combination will improve the quality of patient care and reduce healthcare costs by addressing unmet needs in hospitals, hospital pharmacies and alternate sites of care to increase efficiencies, reduce medication administration errors and improve patient and healthcare worker safety."

Presumably respiratory technologies are covered by "subsequent monitoring" then!

What do all these transactions have in common you may ask? Very simply, you sell off a smaller company hoping to make it attractive enough for a bigger company to want to pay vast amounts of cash for it and, in that way, make a significant return on your investment. It's a bit like fishing really. The only problem is that you aren't sure what is going to appear on your hook and from our point of view whether this leads to the diminution of the status of the PFT and Sleep/ Ventilation business because as a proportion of the total business of the organisation, it becomes very small fry. Generally speaking, in "big business" one of the standard themes with any "acquisition" is to advise your potential investors that the deal will lead to a significant chunk of

"efficiency savings" with integration of sales, marketing and back office typically leading to a reduction in the service that we as consumers have come to expect from the smaller company. This type of thing happens within all big business and Healthcare, of which PFT & Sleep/NIV are just small parts, is no exception.

Around 90% of Cardinal Health's business was box shifting, pharmaceuticals and IT systems. The other few per cent they floated off into CareFusion and so we go into 'For Sale' mode again. CareFusion's dominant market sectors within healthcare are drug delivery devices (Alaris) and automated systems for dispensing theatre trays (Pyxis). (Yes, we know, these are irrelevant to our profession!). We see many drug delivery devices in the UK with Alaris being the market leader but we see little in the way of automated dispensing systems.

The problem for many years with these sort of buyouts is that there has seemed to be a lack of focus on PFT and the fact that the spirometry business was put into the 'Homecare" division within CareFusion could not illustrate the point better. The once market leading brand in spirometry, MicroMedical, has gone nowhere. All Micromedical assets in the UK which is, after all, where this brand was built up, have been effectively liquidated. There has been no spirometer development evidenced to date. Why do you take a market leading brand and do nothing with it? Moving into capital equipment, do these mergers bring an end to significant development of integrated PFT hardware platforms designed to satisfy the users of the previous smaller company systems (e.g. SentrySuite)?

So, turning to Becton Dickinson, known in the trade as BD, let's look at what this company has to offer in turns of research, development and investment for PFT. Well, the announcement of the intent to acquire CareFusion by BD to the stock market tells us that they are purchasing CareFusion for its drug delivery systems. This absolutely makes sense from the BD point of view. They are probably the largest manufacturer of syringes in the world. They are a plastics company and marrying your plastics to your own drug delivery systems which are already dominant in the market, makes business sense.

As the acquisition goes ahead, BD has told the stock market that $250 million in efficiency savings have been identified, where is this going to come from – will it be on anything not connected with drug delivery devices, such as PFT or is 'On The Blower' reading the tea leaves incorrectly?

So what does this mean to ARTP members and the lung function market in the UK? Carefusion is an important player in the PFT market in the UK and at the least should offer assurances that it will remain to compete within the PFT market. Aggressive competition between rival companies being after all what keeps R&D at the forefront, facilitates good service and keeps pricing keen.

'On the Blower' has seen this before, but as mentioned earlier, each acquisition means the loss of expertise and knowledgeable experts at the cutting edge of the business. We suspect expertise may be reduced to a critical level across the whole lung function sector. We once

used to refer to the "Big Four" (Jaeger/ Morgan/SensorMedics/Med Graphics) but it seems we will have perhaps a Big Two or "Little Five". All this doesn't make any sense as we are all aware that physiological diagnostics are in greater demand than ever. Perhaps innovation, disruptive technology and wise investment will be the answer.

AM

Baywatch

Baywater Healthcare, formerly Air Products, was formed via a management buyout with Adam Sullivan, Chief Executive, at the helm in December 2013. Baywater is not only active in the home oxygen market sector but is quietly expanding its interests around procurement departments and CCGs trying to persuade them, that they can provide sleep diagnostics, CPAP and NIV in a much more patient focussed and cost effective manner than we can! You were unaware of this? Well, Baywater have apparently being offering this type of homecare service in Ireland for some time, and they have recently been attending ARTP departments and events.

So, how does Baywater provide a service which will be at a level above any current ARTP department? Surely they have employed a vast team of sleep specialists in both diagnostics and therapeutics? They certainly claim this and reckon they have in excess of 30,000 patients on the books in the UK and Ireland.

As a company, Air Products did not add its signature to the ARTP standards of care for Sleep Apnoea services and decided as Baywater to leave the ARTP Sleep Apnoea Consortium. Further information is required.

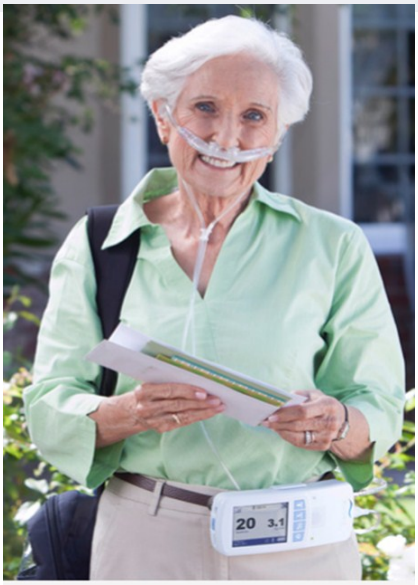
AM

2014 Products of outstanding interest award - ERS Congress Munich

This year's Product of Outstanding Interest (POINT) Awards were presented at the ERS International Congress in Munich by Vivienne Parry, the esteemed UK broadcaster, author and medical correspondent. She delivered a brilliant, entertaining and insightful presentation on "Innovation" to a select audience who were fully engaged with her understanding and experience of innovation in respiratory medicine. The presentation will be available on the ERS website in due course and is well worth following on-line. Details of each of the finalists is covered in the Buyer's Guide article (of which 10,000 were picked up at the Congress!) where you will also find the brilliant article on innovation by Vivienne Parry.

The POINT Awards finalist this year were:

Non-invasive Open Ventilation System (NIOV) www.breathetechnologies.com



The NIOV is a portable, non-invasive ventilator which is the NIV equivalent of ambulatory oxygen, enabling the patient to have portable supportive ventilation. NIOV can be set resting (low), moderate (medium) and exercise (high) activity levels. It requires an oxygen cylinder or other pressurised oxygen source to deliver the pressure so is an adjunct to portable oxygen. It may be run either off mains electricity (when sitting) or using a rechargeable (approximately 4 hours) internal battery while portable. It is connected to a pillows-style nasal interface that just covers the nostrils, leaving the mouth unobstructed for speaking.

Non-invasive Open Ventilation System (NIOV) Neo-Tee Infant T-Piece Resuscitator

www.mercurymed.com

Neo-Tee Infant T-Piece Resuscitator

This positive pressure interface for neonates who require ventilation is the first disposable infant T-Piece resuscitator with a built-in manometer and pressure relief system. The Neo-Tee® is both flow-controlled and pressure-limited and allows delivery of more consistent, targeted Peak Inspiratory Pressure (PIP) and Positive End-Expiratory Pressure (PEEP). The key advantage is there is no capital equipment to purchase and it is completely disposable. It replaces the need to squeeze a resuscitation bag since there is no bag to squeeze. Will this concept catch on for adults as well?

DynaPort Move Monitor www.mcroberts.nl

DynaPort Move Monitor

The Dynaport is essentially an activity monitor for assessing respiratory interventions. It consists of a small (85 x 58 x 11.5 mm), light case containing a tri-axial accelerometer, rechargeable battery, USB connection, and raw data storage (204 hours) on a MicroSD card. It is worn on the lower back where the accelerometer responds to the Earth's gravitational field and uses a seismic sensor which responds to both slow and fast changes in acceleration. These features enable patient posture and motion detection. Its application for pulmonary rehabilitation (PR) and patient activity monitoring adds a new dimension to monitoring and understanding patient's habitual activity, thus aiding the impact of therapeutic interventions such as PR, ambulatory oxygen or new medication. It has good reproducibility (<3.1%) and a good intra-observer intraclass correlation coefficient (0.93-0.98).

Bronch Mentor www.simbionix.com

The BRONCH Mentor is an innovative addition to a line of medical simulators which provides a comprehensive training solution for flexible bronchoscopy.

Whilst this is not an actual diagnostic device itself – simulators for training in diagnostic techniques are as important as the new devices themselves. Basic skill tasks and complete clinical procedures are combined to provide an optimal learning environment for motor, cognitive and coordinative skills acquisition on one hand, and diagnostic and therapeutic clinical hands-on experience on the other. It provides a flexible, all inclusive and highly reactive training environment for the end user.

Bronch Mentor

From these four finalists we announced the winners, but in all honesty, all four products should be praised for their innovation, development and novelty. The winners were;

Therapeutics Award: Neo-Tee Infant T-Piece Resuscitator (Mercury Medical)

Diagnostics Award: DynaPort Move Monitor (McRoberts)

We are now planning for next years Innovation awards and we look forward from hearing from ERS members, officers, manufacturer's and practitioners in every area of respiratory care about next years nominated devices for our panel to review.

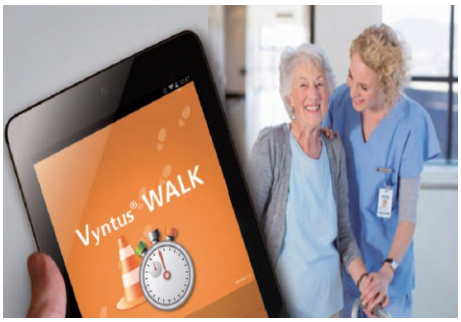
BC

Is this the world's smallest CPAP machine?

Breas and HDM (Human Design Medical) are now part of the same company and have produced the world's smallest CPAP, the Z1. Weighing just 284 grams, it fits in the palm of your hand but can power up to 8 hours of CPAP. It is ideal for those who like to use portable CPAP wherever they are sleeping, be it camping, on long haul flights, or wherever and whenever. It is approved by the FAA for in -flight use. Whilst it is not cheap, at around £460 (additional battery packs are extra), it is likely to be popular with regular travellers.

NC

Carefusion



Stuart Bennett has returned to Carefusion as UK sales and marketing manager. Good to see him back and we wish him the best in his new role. Carefusion are publicising their Vyntus Bluetooth communicating CPX, ECG and simple exercise testing kit which should allow for more paperless diagnostic reports. Hopefully this may give more choice in the wireless market, as watching physiologists chasing patients up our six minute walk corridor is amusing but does need to be brought into the current century.

SW

Aerocrine

As I'm sure most of you know (see Aug. 2014 Inspire OTB), NICE guidance was produced this year for the use of Nitric Oxide (NO) in the diagnosis of asthma. Aerocrine is a company similar to NDD in that it was born from a university research project. The founders of Aerocrine studied at the Karolinska Institute in Sweden where they were the first to identify NO as a marker of inflammation.

Aerocrine has now developed the Mino and

Company News

produced a user / patient friendly NO analyser called the NIOX Vero. There's even a video presentation for those that have moved into the current century, (unlike myself). Aerocrine products are now distributed in the UK by Health Care21

SW

Fisher & Paykel

F & P have a new offer on two masks; the Simplus and Eson: Both of which can come with an extra seal for just £5 more. They are also offering 25% off on a customer's first order.

"The F&P Simplus incorporates three key components, the RollFit™ Seal, ErgoForm™ Headgear and Easy Frame, all designed to work in harmony. In combination, these components offer the comfort, seal and easy use that Fisher & Paykel Healthcare masks are known for."

SW

Medica

On a equipment related note, nearly 5000 manufacturers were involved with the recent Medica conference trade show in Dusseldorf. Continuing the theme of

Alan's article this month, it illustrates again in how much of a global village the UK Healthcare Science industry is a part of. Medica's press release stated that 85% of German manufacturers surveyed believed that medical device sales will continue to rise but fuelled by an increase in purchases from emerging economies, suggesting that medical equipment may be more tailored to the Chinese, Indian and Brazilian markets as the world economy moves forward. **SW**

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Date of Preparation: December 2014
OS/UK/2014/045

LUNG FUNCTION TESTING IN TRACHEOSTOMY AND LARYNGECTOMY PATIENTS

PART II – A REVIEW AND PRACTICAL GUIDE

Adrian H Kendrick, Consultant Clinical Scientist, University Hospitals, Bristol

Introduction

This second part of the review will attempt to reassure readers that patients with a tracheostomy or laryngectomy can undertake potentially a wide range of lung function tests. This article will therefore review the practicalities of making the measurements of lung function with relatively simple adaptations to connect the measuring device to the patient. It is my view that these patients just provide a challenge in a different way to most other patients coming through a lung function laboratory, whether this is for adults or for children.

When a patient presents to the department with a tracheostomy or a laryngectomy, the physiologist has some interesting challenges. The first will be that hopefully the referring practitioner has remembered to state this minor technical problem on the request form, so that the necessary circuit changes and adaptations can be in place before the patient arrives – it sort of avoids embarrassment! The other issue, in this time pressed, production line type system of assessing patients is that these patients will take longer for their appointment. It may be prudent to actually double the appointment time to, in the first instance, work with the patient to get the circuit adaptations in place and then to undertake the tests within the patient's capabilities. Explaining this to some of the administration staffs and non-clinical managers though – especially those running time-limited pathways, may be more challenging than actually seeing the patient and doing the tests!

Most tests in a lung function unit require an adequate seal to make the measurements viable and technically acceptable. There is also the lovely issue of dealing with the upper airway secretions, which normally would move slightly further up the upper airway and then be swallowed. This will present some potential issues, and doubtless your Infection Control department will have a desire to express their clearly evidenced-based thoughts on the matter! The final issue that is important is understanding how the upper airway structure has been changed and therefore the interpretation of the data obtained from the studies will need to be assessed, in the light of these changes. These potential changes were outlined in Part 1[1].

It is the view of this author that these patients present a different challenge, the answer should always be – can do, take a breath in, and get on with it!

The Revised Upper Airway

In Figure 2 of Part 1 of this review[1], we saw what the revised upper airway looks like. It is shortened and many of the processes undertaken by the upper airway are removed or reduced. This revised upper airway may present in two broad forms – those with a tracheostomy tube in situ and those with simple a hole (Figure 1). Both of these present differing problems which are relatively easily solved with time and application.

Post-Surgery Studies

There are a number of studies that have assessed lung function indices in patients post-surgery and where the patient has either had a tracheostomy or a partial or full laryngectomy and which provide evidence of altered lung function[2-24]. What is clear is that it is difficult to determine, how the surgical procedure and the pre-surgical lung status may have affected the post-operative lung function, particularly of the upper airways.

Whatever test is required, the first problem faced by the physiology team is how to connect the equipment to the site. If there is a tracheostomy tube in situ and this tube is of the right type, then it should be feasible to connect most equipment to the site with a degree of adaptation of the circuitry, time and ingenuity. What is important with the adaptation is to ensure that you understand precisely what effect the adapted circuitry will have on the test you wish to undertake. So, for instance where you need to do CO Diffusion studies, there is an assumed dead space of the system which normally contains equipment dead space and anatomical dead space. You are likely to increase your equipment dead space and you will reduce your anatomical dead space – do they roughly balance each other out? – read onto the section on CO Diffusion studies! More difficult is the patient who simply has a hole, i.e. a laryngectomy as there is no obvious way of connecting anything directly to the site (Figure 1).

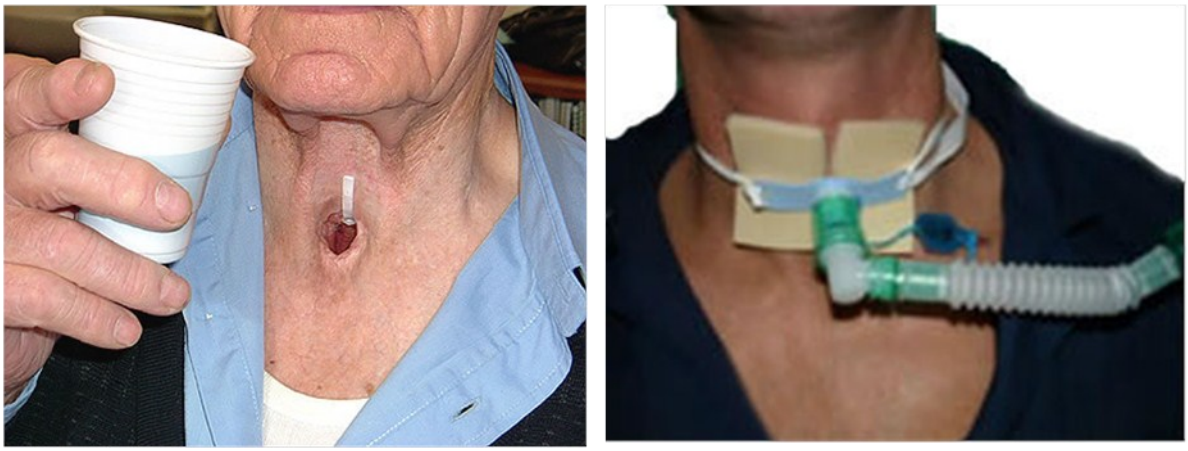

Figure 1. On the left is a laryngectomy – a hole with no easy way of directly connecting anything to the site to provide an airtight seal. On the right is a tracheostomy in situ with the ability to externally connect to the site. *Images from ranadasaha.wordpress.com and theprincespost*

Connections via Tracheostomy

This should be simple as we know we can easily connect a non-invasive ventilation (NIV) circuit or cough assist device directly to the tracheostomy tube (Figure 2). The other connection for the management of patients with a tracheostomy is the use of incentive spirometry (Figure 3), which may be used to improve inspiratory muscle strength[25-28], However, this is only part of the issue. Tracheostomy tubes come in various types, and ensuring you have the right tube will allow you to make the

Figure 2. Two examples of patients connected to ventilatory and airway clearance devices. On the left is a patient attached to non-invasive (!) ventilation via a tracheostomy. On the right is a child using a cough assist device that allows excess airway secretions to be removed when the cough reflex is poor. Measurements of cough peak expiratory flow (cPEF) provide a guide to the weakness of the cough, but attachment of the PEF meter to the tracheostomy site is firstly required!

measurements properly (Figure 4).

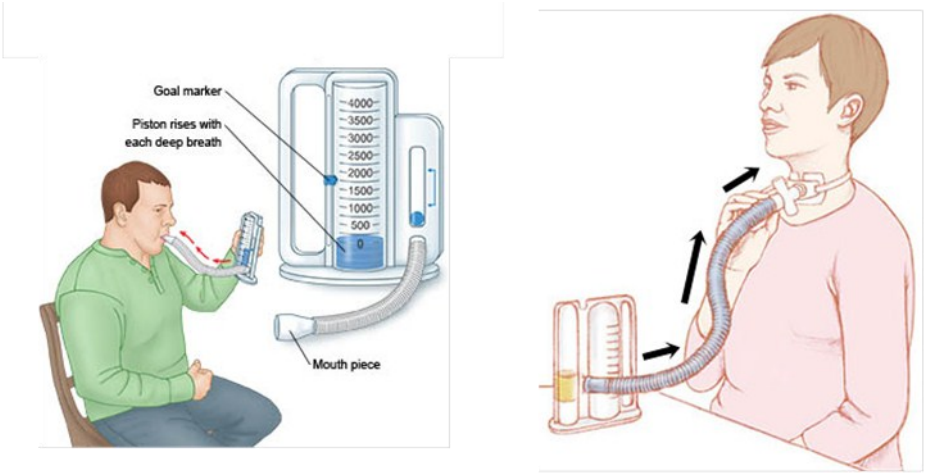

Figure 3. Incentive spirometry shown on the left via the mouth and on the right via a tracheostomy.

Images from www.drugs.com and www.mountnittany.org

There are three key types -

Cuffed Tube: Patients who need ventilation require a tube that is blocked and sealed by a cuff (effectively an inflated balloon) located on the lower outer cannula. The cuff prevents air flowing around the tube, so that all of the air will flow in and out through the tube itself. A pilot tube attached to the cuff stays outside the body and is used to inflate or deflate the cuff. Generally this type of tube will be used with lung function testing as we need to maintain a seal, thereby reducing leaks etc.

Fenestrated Tube: This tube has an opening – a fenestration in the back of the outer cannula. The front of the tube can be blocked which allows the air to flow upwards to the upper part of the trachea and larynx. This type of tube allows the patient to breathe normally through the upper airway, and enables them to speak and cough through the mouth.

Cuffless Tube: These tubes are used in non-ventilated patients that have no difficulty swallowing and have no danger of aspiration. There is no cuff, so air can pass into the upper trachea and

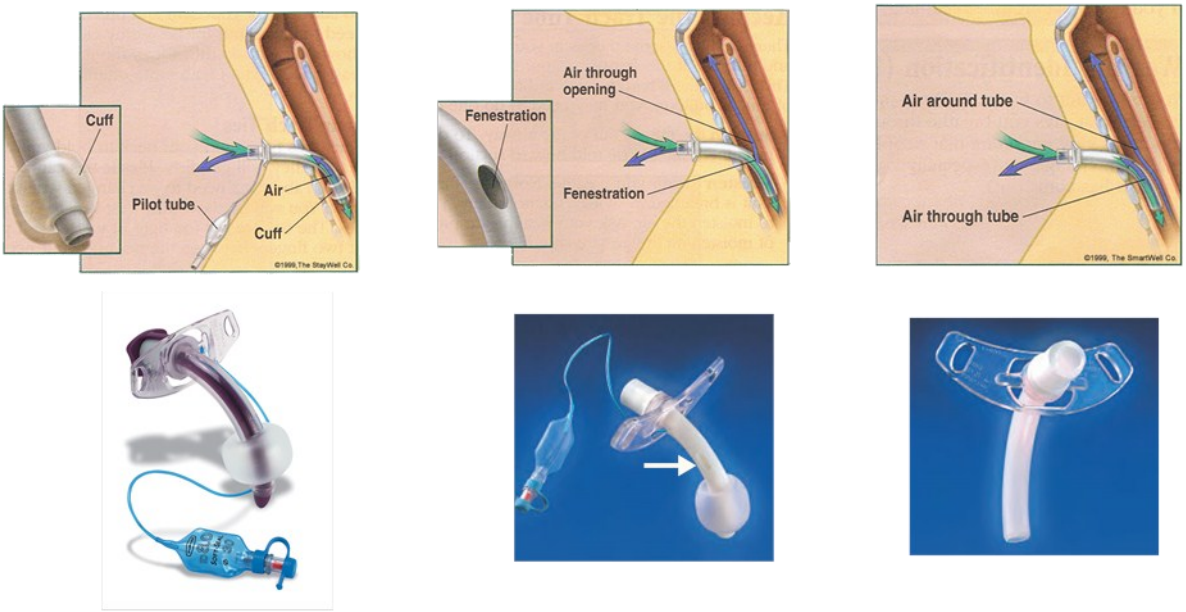

Figure 4. Examples of the cuffed, fenestrated and cuffless tracheostomy tubes. See text for details of differences. *Diagrams from http://trachs.com and various manufacturer websites.*

larynx allowing the patient to cough and speak normally. These tubes are usually worn over a long period of time so require a very accurate fit to prevent pressure sores either in the trachea or at the tracheal stoma.

Other Tube Types: Most of the tracheostomy tubes produced today are plastic and it is relatively easy to connect external devices directly to the site (Figure 5). However, there remain some patients who use metal (silver) type tubes and these present difficulties in connecting even a non-invasive ventilator to the site.

The very first patient I had to set-up on home NIV had a silver tracheostomy system in place. We had to train her to change the silver tube for a plastic tube every night to enable her to use her NIV system. She lived alone in a rural community, self-cared and survived for about 5 years very successfully. It was an interesting challenge and she was a fascinating and determined lady – just the excellent and wonderful type of patient you want on your first ever home NIV set-up!

Figure 5. Silver (metal) tracheostomy tube shown on the left with the outer tube, inner tube and guide shown from right to left. In the picture on the right side, exactly the same components are observed, the tube being a cuffed type, but the key difference is the connector (arrowed) which will allow connection of equipment directly onto the tube.

How to Connect: The key issue that you will have is connecting the equipment to the tracheostomy tube, as the tubes themselves come in different external diameters and there may be differences between manufacturers. There is also the issue of differences between sizes in relation to adults and to paediatrics. To connect the tracheostomy tube to the equipment will therefore require a range of connectors and tubes (Figure 6).

In the first instance the internal diameter of the test equipment needs to be assessed and then the potential ease of connecting anything to this. It is essential to interface the equipment to the patient with a bacterial filter in situ. This will protect the equipment from the potentially excess secretions that are likely to be present in the revised upper airway. However, you will need to make sure that the filter does not increase the resistance of the circuit too much. The filter, itself, may well provide a suitable connection to the equipment, so that the only interfacing required will be between the tracheostomy tube and the filter.

Figure 6. Range of connectors that may be used to interconnect the site to the equipment. These include a range of straight and angled connectors, smooth bore tubing, tracheostomy mounts (various types and sizes), HME baseplates and non-disposable medically tapered connectors. Images from various sources. The author does not specifically use or support any companies whose products may be illustrated in this picture.

Connections via Tracheostomy

We know from the previously published studies that is it possible to connect the patient to undertake a range of tests [2-24], including cardiopulmonary exercise testing[2, 7, 18]. Two recent publications[29, 30] have highlighted the potential ease with which such patients can be readily attached to spirometry equipment and are similar to that used previously[31]. Essentially all of these papers use the base holders of a heat and moisture exchanger which stick onto the surface of the skin and can be connected to the equipment (Figure 7). Whilst these three papers have only measured dynamic lung volumes, there is no reason why this technique cannot be extended to other measurements with relative ease.

Spirometry

Tracheostomy: If you can connect a tracheostomy patient to an incentive spirometer, you can equally connect a normal spirometer to a tracheostomy tube (Figure 8). Simply the patient has to forcibly exhale via a cuffed tracheostomy tube in exactly the same as they would if they were undertaking the manoeuvre via the mouth.

However, there is one important issue to be taken into account. Tracheostomy tubes are not 22 mm to 25 mm internal diameter and therefore the flow dynamics will be affected. If we use Poiseuille's law

$$P = \frac{8\mu L\dot{V}}{\pi r^4} \quad (1)$$

Figure 7. Top; Connection devices used to connect patient to spirometry equipment. Bottom; connections in situ and attached to spirometer.

Images from reference 30.

and we know that

$$P = \dot{V} \times R \quad (2)$$

where P is the pressure difference, L is the length of tube, μ is the dynamic viscosity, $\dot{V}$ is the flow, r is the radius of the tube, π is the mathematical constant Pi and R is the resistance. If these two equations are combined and then re-arranged for R, we get -

$$R = \frac{8\mu L}{\pi r^4} \quad (3)$$

This means that the resistance is inversely related to the radius to the fourth power. In other words, halve the radius, the resistance increases 16-fold. If you increase the resistance, and the pressure difference remains constant, then the flow rate must decrease, with the net result that measurements such as PEF will be affected by the radius of the tracheostomy tube. This is not quite that simple though, as in the upper airways you have turbulent flow and where the Reynold's number exceeds 2100, turbulent airflow occurs. The Reynold's number is estimated from the various factors including flow rate and resistance.

What this therefore means, is that measurements at high flow rates are likely to be affected by the presence of the tracheostomy tube, as well as any additional scarring around the site and within the upper airway. This is very important when it comes to interpreting airflow measurements and a clear understanding of how the airflow dynamics have changed from normal airway dynamics is essential.

This of course, only applies to dynamic airflows. A relaxed VC, where there is going to be less resistance to airflow should not be significantly affected.

Laryngectomy: This is actually easier to undertake using the adaptations shown in Figures 7 and 8. As the internal diameter of the tubing is 22 to 25 mm, the effects of the circuit

on the measurements will not be so difficult, or indeed affected by the resistance that a tracheostomy circuit presents. Typical flow-volume curves were illustrated from previously published work in Part 1 of this review[1].

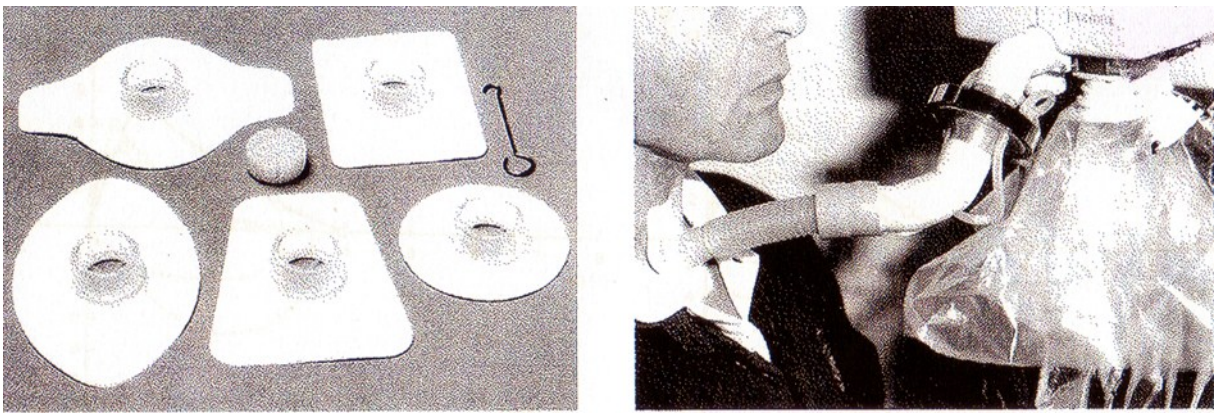

Figure 8. Range of connector base plates shown on the left from heat moisture exchange units (HME). In the centre is the HME cassette and on the right is the hook, used to remove the cassette by the patient. On the right is a patient directly connected to a flow head from a standard commercially available lung function equipment. *Images from reference 31.*

Assessment of Bronchodilator response

Where a patient requires assessment of inhaled medication or indeed needs to regularly use inhaled medication, the revised site presents some interesting problems.

Metered Dose Inhalers (MDI): Standard MDI's are designed for oral use, and the size of the particles produced would allow them to 'stay airborne' during transportation along the upper airway and beyond. This theory is of course limited by the shape and dimensions of a normal upper airway, with a significant amount of drug being deposited onto the pharyngeal and laryngeal mucosa, and therefore will not reach the trachea and bronchi, where we wish the medication to exert its effect.

Perhaps surprisingly, there is a remarkable dearth of data on delivering drugs via tracheostomy[32 - 38] in such patients, other than when they are ventilated in an ITU, for instance.

Some of the publications have investigated nebuliser aerosol delivery using bench models[35]and based their study on four key issues in optimizing delivery through such an artificial airway. These are:

1. the pattern of ventilation and the timing of aerosol delivery
2. the carrier gas properties
3. the nebulizing device and
4. the circuit properties[36].

Aerosol delivery is improved with a slow inspiratory flow and large tidal volume, timing of aerosol delivery to the inspiratory phase, a dry carrier gas, an efficient nebulizer, and a holding chamber with MDI use. In this bench study, the authors noted that delivery varied by from 1.4% to 15.3% and that this was dependent upon the configuration of the circuit.

For many patients who only require the use of an MDI with or without a spacer device, this is preferred to nebuliser devices due to the portability of these devices, despite the slightly poorer deposition that may be encountered.

Delivery directly from the MDI directly into and through the stoma, is almost certainly suboptimal. Use of a spacer-type chamber which is directly attached to the stoma, and in essence will replicate the use of the spacer device orally would be sensible and ideal. Recently, Berlinski and Chavaz[37] have used a paediatric model to assess how different devices – Aerotrach Plus, Medibag, Aerochmaber MV, Aerochmaber Mini and an inline adaptor, work in terms of drug delivery. In simulated 16 month, 6 and 12 year old children, they observed that the Aerotrach Plus (Figure 9) outperformed all of the other systems tested

Whilst some devices may be fitted directly onto the tracheostomy tube, other devices may need to be adapted, where there is simply a hole following laryngectomy (Figure 10). Again a spacer device seems to be a logical approach to this, and makes use of the Provox HME adhesive to directly link the peristomal area to the spacer device as shown in Figure 7.

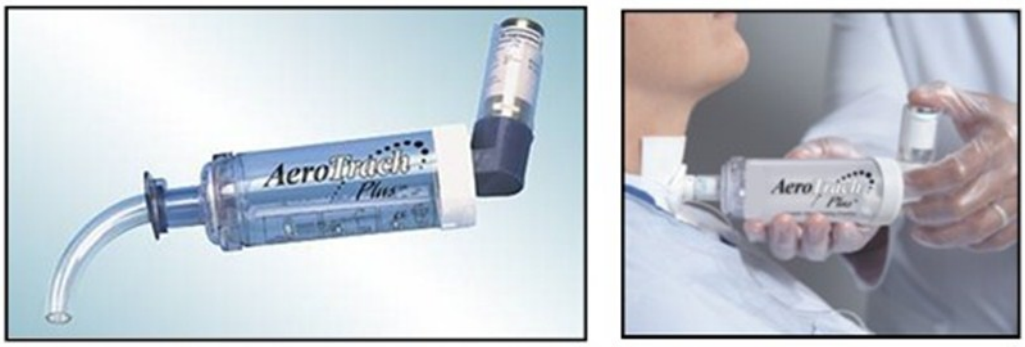

Figure 9. The Aerotrach plus device shown with a metered dose inhaler connected to a tracheostomy tube (left) and then the system in situ on the right.

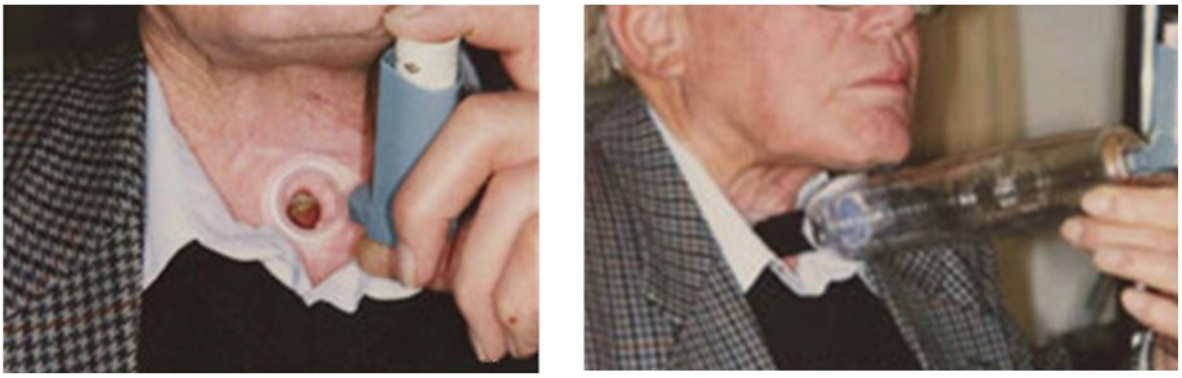

Figure 10. Adaptation of the use of a spacer device with metered dose inhaler to deliver inhaled therapy in a patient with a laryngectomy. Source of images unknown.

Nebulisers: Whilst there is clearer evidence that nebulisation of inhaled medication works via a tracheostomy site, most of the data is based on those patients who are mechanically ventilated[39 - 44]. There is also data centred on children[45 - 50], and some studies again using In Vitro modelling[48].

In a recent survey, Willis & Berlinski[45] noted that there was a diverse range of methodology used to deliver nebulised medications in spontaneously breathing children, with poor documentation and a

range of devices used. One conclusion that generally seemed to be a consensus was that the choice of device depended on patient ability and co-operation[47]. It was certainly interesting the range of devices reported (Figure 11) and the reasons for their choice (Figure 12).

Logically, similar approaches would be observed in adults, with the need for careful connection to the tracheostomy tube or to the site.

Dry Powder: Dry powder inhalers may be used as an alternative therapy in airways disease. A single study has assessed the potential for delivering dry powder inhalers via a tracheostomy tube[51], by adjusting the circuitry using a variety of interfaces (Figure 13). The majority of patients (19/23) were able to generate sufficient inspiratory flow to be

Figure 11. Left: Examples of devices used with metered-dose inhalers. From left upper to right lower: valved holding chamber (unassisted); spacer (unassisted); spacer with flow-inflating bag (assisted); and spacer with self-inflating bag (assisted). Right: Examples of nebulizer devices. From top to bottom: continuously operated jet nebulizer placed between a self-inflating resuscitation bag and a 6-inch corrugated tube (assisted); jet nebulizer with tracheostomy mask (unassisted); jet nebulizer placed between a flow-inflating resuscitation bag and a 6-inch corrugated tube (assisted); and jet nebulizer connected to a 6-inch corrugated tube (unassisted) From Willis and Berlinski[45].

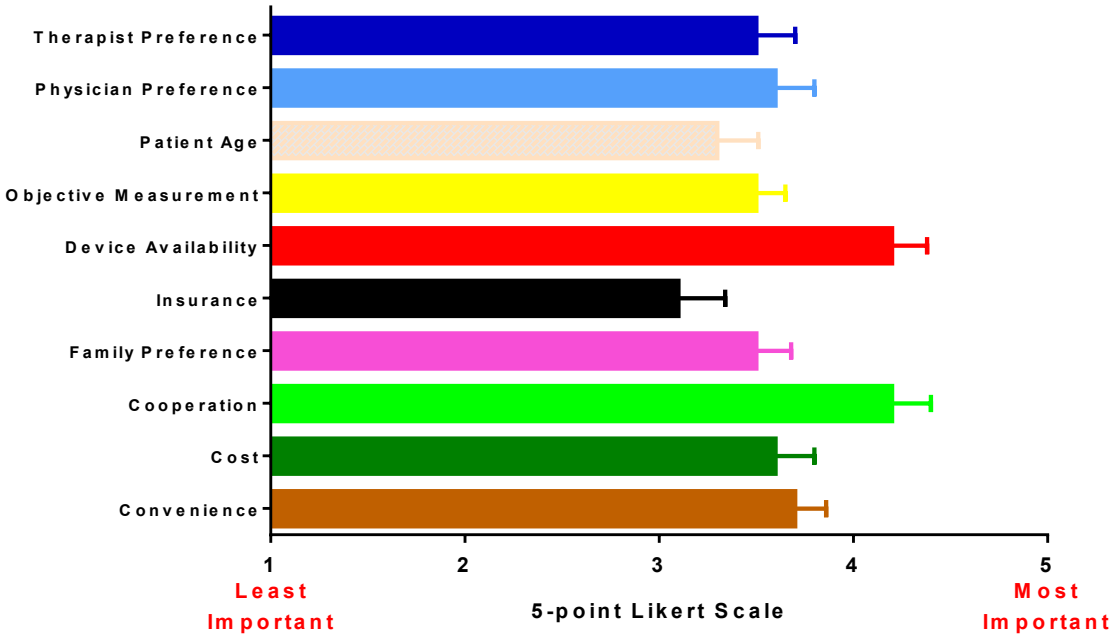

Figure 12. Mean ± SE of 38 responses regarding choice of device. Device availability (19/38) and Cooperation (n = 22/38) were regarded as "Most Important" by the respondents. Data from Willis & Berlinski[45].

able to use the adaptations without assistance, whilst the remaining 4 patients required additional inspiratory support. Whilst no further studies appear in the peer-reviewed literature, the issues of particle size and dose delivery remain unclear.

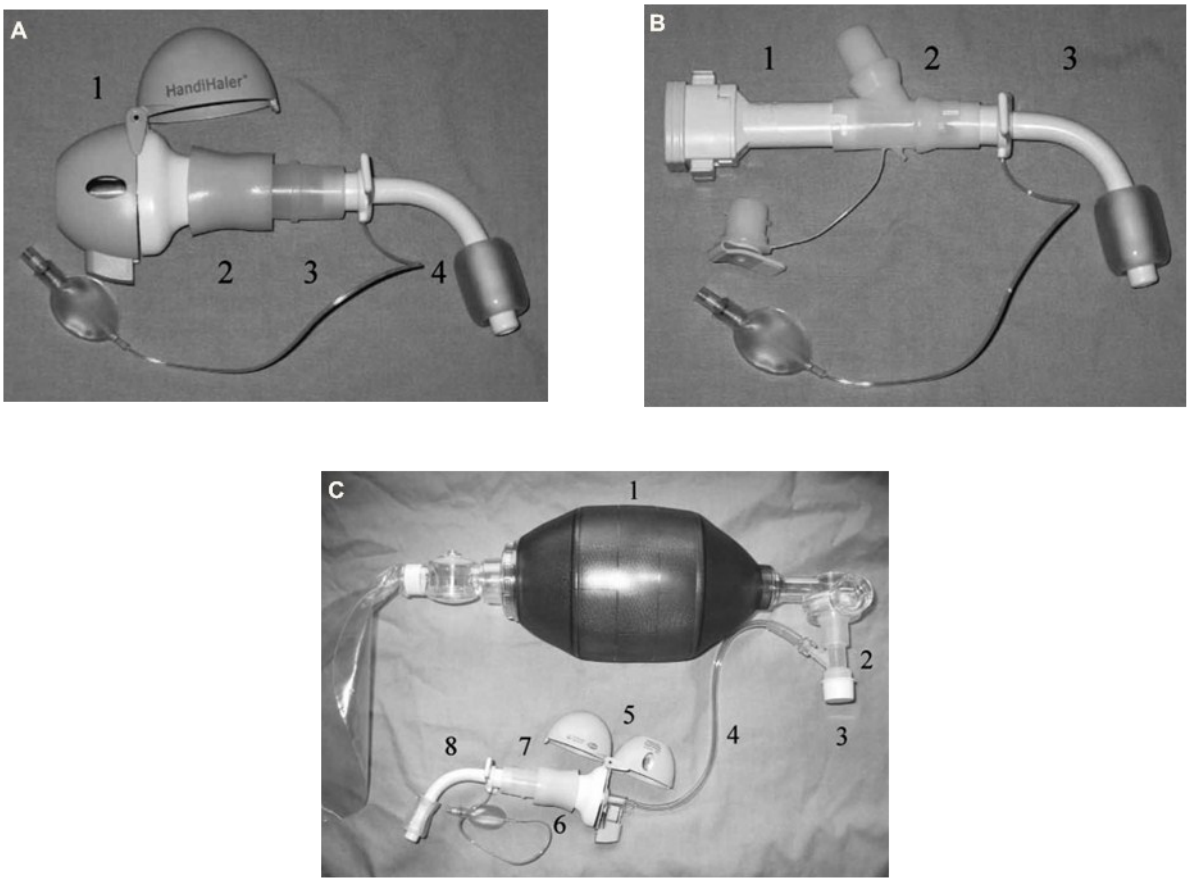

Figure 13. Three set-ups to deliver dry powder inhaler to patients via tracheostomy. A) Delivery using Handihaler (1) via 22 mm ID silicone connector and 3) 22 mm OD plastic adaptor to 4) the tracheostomy tube. B) Delivery using 1) Aersolizer, via 2) silicone connector to 3) tracheostomy tube. C) Bag-assisted delivery showing 1) manual resuscitator, 2) T-piece, 3) cap, 4) tubing, 5) Handihaler, 6) silicone adaptor 7) plastic adaptor and 8) tracheostomy tube. Images from reference 51.

studies via tracheostomy.

It should be feasible to connect the patient via the tracheostomy to the test equipment as for spirometry above. This will produce a circuit that has an increased equipment dead space as an extension tube will need to be placed between the equipment and the connection onto the tracheostomy tube. However, you will now be starting at a lower value for the anatomical dead space, having removed the upper airway component.

In the calculations to estimate CO Diffusion, review

CO Diffusion

This test presents some potentially interesting problems more in terms of the calculations than in the undertaking of the test. Interestingly, none of the previous studies have undertaken CO Diffusion

of the calculation needs to be undertaken and in particular the estimation of the alveolar volume (VA) –

$$V_A = (V_I - V_D) \times \left[\frac{CH_{4,out}}{CH_{4,in}}\right] \quad (4)$$

where V_I is the volume inspired, V_D is dead space and CH_4 is the "inert" gas. The component V_D consists of 2 subcomponents – the anatomical dead space of the airways that do not participate in gas exchange, i.e. the conducting airways, and the dead space of the equipment. The problem therefore is

how you adjust for the changes in dead space as the anatomical dead space of the subject has technically decreased whilst the equipment dead space will have technically increased. So, is this more a theoretical exercise or is there really an issue?

In the ATS/ERS Guidelines for CO Diffusion[52], the authors highlighted the issues of both the equipment dead space and the anatomical dead space. The equipment dead space should be known and supplied by the manufacturer, and this must include the addition of the filter, and for this group of patients, the tube extension. Importantly, the authors state that this should be less than 350 mL, although precisely the source of this figure is not stated. In terms of the anatomical dead space, this can be estimated, as recommended, by either of the following equations –

If BMI < 30 $kg.m^{-2}$

$$V_D = 2.2 \text{ mL} \times \text{Body Weight (kg)} \quad (5)$$

If BMI > 30 $kg.m^{-2}$

$$V_D = 24 \times \text{Height (cm)} \times \text{Height (cm)}/4545 \quad (6)$$

Equation 6 also applies where body weight is unknown, but do not expect the same answer as the estimates are not directly interchangeable. So for an 86.7 kg male of height 170 cm, equation (5) gives 190.7 mL and equation (6) gives 153 mL, but the BMI is exactly 30 $kg.m^{-1}$. We also know that these calculations, in relation to the original data obtained from direct measurement by the Fowler method are not accurate [53].

To confuse things slightly further, these calculations do not appear to be relevant to infants and children, where the ratio of $mL.kg^{-1}$ should be estimated, according to Numa & Newth[54], from –

$$V_D = 3.28 - 0.56[\ln(1 + \text{age})] \quad (7)$$

Interestingly, the ratio of 2.2 $mL.kg^{-1}$ for an adult aged 18 years, does not equal the estimated ratio from equation 7, as this is estimated at 1.63 $ml.kg^{-1}$. Further anatomical dead space alters with increasing age in adults, but 2.2 in non-obese subjects will suffice for the moment. So nothing is perfect!

So, how much difference to anatomical dead space would a tracheostomy tube, cuffed and in situ make to the dead space overall? Firstly, account needs to be taken of the oral cavity volume, where the oral cavity is defined as - the part of the mouth behind the gums and teeth that is bounded above by the hard and soft palates and below by the tongue and by the mucous membrane connecting it with the inner part of the mandible. Using MRI scans in normal subjects the approximate, averaged oral cavity volume is about 21 mL [55].

The second issue is the volume of the conducting airways, and in particular the trachea. If we apply volume calculations using the Weibel model of the bronchial tree[56] in an adult, then the estimated volume of the trachea *(calculated from $\pi r^2 L$, where r is the radius of a tube and L is the length of the tube. The radius of the trachea is 0.9 cm and its length is 12 cm, giving a volume of 31 mL, based on Weibel's data.)* is approximately 31 mL.

The majority of the trachea (» 8 cm) would be included within the tracheostomy tube and beyond, so the reduction in this volume would be minimal and would equate to about 11 mL. Therefore, and perhaps surprisingly, at first, the volume of dead space ventilation lost by the insertion of a tracheostomy tube will be around 32 mL, allowing for the volume of the tracheostomy tube inserted. So the actual total dead space that needs to be account for in the calculation of V_A (Equation 4) will include a) device volume, b) filter volume, c) tubing extension volume, and the actual anatomical dead space less about 32 mL. So the overall length of tubing that equates to a 32 mL volume, using a 1.50 cm internal diameter tube would be around 18 cm in length, reducing to 8.5 cm for a 2.2 cm internal diameter tube. In other words, it makes little or no difference to the actual dead space volume, so long as the internal diameter of the tube is known, its length can be calculated.

Static Lung Volumes

As most commercially available lung function equipment now use an integrated flow head to measure all of the key basic tests in lung function, once an adaptation of the circuit for spirometry and CO Diffusion been achieved, the same circuit can be used for multi-breath helium dilution, nitrogen washout and body plethysmography[57]. A cuffed tracheostomy tube would be essential to ensure a good seal.

Gas Dilution & Washout Measurements

One study has assessed static lung volumes using helium dilution[10]. In terms of the measurements by multi-breath helium dilution, it would be normal in some systems to estimate the dead space of the circuit. As described above, the loss of oral cavity dead space and part of the upper trachea can be easily compensated by the connection tube used between the filter and the connection, whether this is attaching to a tracheostomy tube or to the HME baseplate in a laryngectomised patient. Clinically, so long as the differences remain small – 50 mL to 100 mL, this will essentially make little difference to the clinical interpretation of these measurements.

The key issue is to maintain a seal for the duration of the test. It will therefore be very important to closely watch the pattern of the dilution of the gas over time.

Body Plethysmography

Static lung volumes are probably easier to measure using this technique and have been used in laryngectomy patients previously[7, 12, 23].

This techniques measures all of the compressible gas within the airways, assuming an open glottis. It is reasonable to assume that this remains the case either via a tracheostomy tube or via a laryngectomy connection. As the measurements take only a few seconds each to complete, and the static lung volume measurement to obtain VC is a relaxed manoeuvre, this technique will also cause less distress to the subject. As with all measurements, the operator needs to review the resultant traces to ensure technical accuracy of the measurements, rejecting those that are questionable.

Resistance Measurements

These may be of perhaps more importance in monitoring long-term changes as they are sensitive to changes in airway geometry[58, 59].

Usui[9] used the forced oscillation method of Mead in patients post laryngectomy and showed that these patients had a significantly higher resistance compared to normal subjects, Furthermore, after ultrasonic nebulisation there was a significant decrease in the resistance in the laryngectomised patients. Davidson et al[15] used oscillatory resistance (Ros) via a tracheal stoma, and using a body plethysmograph (Raw). In one patient they demonstrated clinically significant changes in both indices post-surgery compared to the pre-surgical values–Raw; 5.0 to 0.7 $cmH_2O.L^{-1}$ and Ros; 6.0 to 2.3 $cmH_2O.L^{-1}$.

The application, therefore of airway resistance, whether measured by body plethysmography, forced (FOT) or impulse oscillation (IOS) potentially provides a simple, assessment of airway status without the need for forced expiratory manoeuvres. However, there may need to be a greater understanding of the effects of changes in the airway geometry, especially in those patients with a tracheostomy[60].

Maximal Inspiratory (MIP) and Expiratory (MEP) Pressures

One study has measured mouth pressures during mechanical ventilation[28] as part of an inspiratory muscle training study and showed small, non-significant differences.

Technically, these tests are not difficult in the intubated, conscious and co-operative patient. This author has previously assessed one patient over a two to three weeks using a handheld device, where the ITU wished to assess changes in muscle strength in a patient who had

significant acute neuropathy and was tracheostomized. As the clinical status of the patient improved, so did the MIPS and MEPS, starting at very low values and gradually improving over time. Eventually the patient went home, without a tracheostomy, and reasonably well preserved MIPS and MEPS.

Attachment of the MIPS and MEPS device should be relatively easy to a cuffed tracheostomy tube, and similarly to the HME baseplate in patients with a laryngectomy.

Hypoxic Challenge Test (HCT)

Many patients wish to fly and those patients with a tracheostomy or a laryngectomy may need to undertake a hypoxic challenge test to assess whether or not they require supplemental oxygen in flight. Interestingly, the current British Thoracic Guidelines appear not mention such patients, so presumably these patients do not appear to present a problem[61].

The author has undertaken HCT studies on a number of patients with a tracheostomy in situ without any untoward difficulty. Using a cuffed tube, and attaching a Douglas bag containing 15% O_2 in nitrogen and a two-way non-return valve attached via a filter to the tracheostomy tube directly. In the most recent patient, this was a 15 month child with incurable cancer flying home to central Africa. The circuit used is shown in Figure 14. A similar circuit can used in adults, with a larger two-way non-return valve being used. In laryngectomy patients, attaching the two -way non-return valve to the site could be achieved by use of adhesive plaster, thereby creating the necessary seal. Alternatively, using the 40% venture mask, modified to fit over the stoma site, and 100% Nitrogen could equally work, on the assumption that the flow dynamics of the normal mask are not significantly compromised and hence the patient is actually receiving approximately 15% inspired O_2.

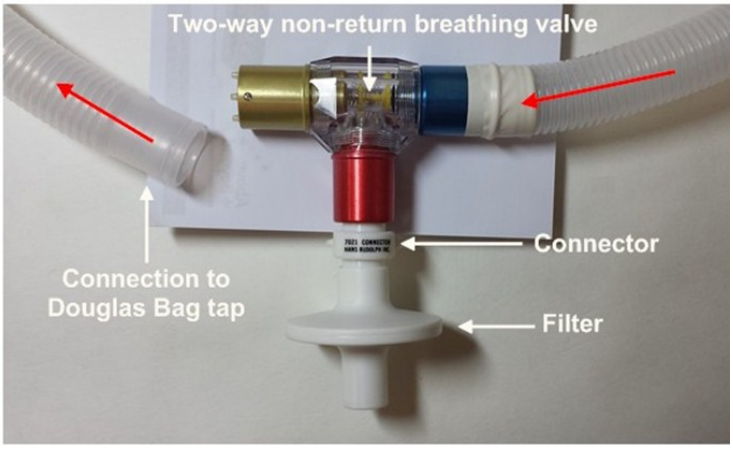

Figure 14. Adaptation of a circuit to allow a hypoxic challenge test in a 15-month child via tracheostomy. The filter came from an exhaled NO system (Medisoft), the connector is from a kit of Hans Rudolf connectors and the two-way non-return breathing valve came originally from a Morgan Model-B Transfer test system (from the 1980's) and was used to allow measurements of subdivisions of CO Diffusion. The connection to the Douglas bag was using standard 22 mm corrugated plastic tubing, to a bi-directional tap allowing the patient to either breathe room air or 15% O_2 from the Douglas bag. The patient desaturated within a couple of minutes to around 80% and was supplied with supplement O_2 via one of the side ports (not visible) on the Hans Rudolf connector. Moral – never throw anything out if it might be useful one day! The red arrows indicate the direction of flow of air/test gas.

Cardiopulmonary Exercise Testing (CPET)

Patients with a laryngectomy or a tracheostomy undertake exercise during their normal daily lives. This exercise may be limited, particularly in tracheostomy patients, but there are certainly some patients able to continue their lives and have a good quality of life, as judged by themselves. So, in these two groups of patients, is CPET testing possible?

Laryngectomy Patients: Three studies have reported CPET testing in this group of patients[2, 7, 18]. In Heyden's[2] study, the precise details of which are unclear, measurements of VO_2, minute ventilation and pulse rate were made, and no significant effects of laryngectomy on exercise performance was observed.

Harris & Jonson[7] measured minute ventilation, breathing pattern and oesophageal pressure by adapting an air-tight soft mask which was placed around the stoma for brief periods of time at each workload using a cycle ergometer. Arterial blood

gases were also performed. The patients managed to complete the test without undue difficulty.

In Gardner & Meah's study[18], a modified rubber mouthpiece was used to measure breathing patterns and the continuously sampled PCO_2 and PO_2 during cycle ergometry. The main purpose of this study was to assess in detail the breathing pattern. No measurements of VO_2 appear to have been made.

All three studies, appear to be technically feasible, and with modern adaptations to connecting the stoma site to the equipment, this should present little or no real technical difficulty.

One potential problem that would need careful consideration is the length of the connecting tube, as technically this will increase the deadspace of the circuit and therefore potentially increase the PCO_2. With breath-by-breath monitoring systems, this could easily be assessed, and with some adaptations, it would be possible to attach the flow transducer very close to the stoma site. However, the other key problem would be the potential presence of excess secretions, which may have an adverse effect on the performance of the flow transducer. Unlike resting measurements of lung function, where a bacterial filter can be used, this is not feasible during exercise as the increased resistance will adversely affect ventilation, being likely to increase the perception of dyspnoea[62].

Where exercise performance is essential, such as part of a pre-operative assessment, then in this group of patients, with careful adaptation of the circuit it should be feasible to undertake both treadmill exercise and cycle ergometry to measure VO_2 and heart rate peak during incremental exercise testing.

Tracheostomy Patients: There appears to be no peer-reviewed studies undertaking formal maximal CPET testing via a tracheostomy. This is perhaps this is not surprising as technically this may provide some significant challenges. Despite this, we know that patients are able to undertake exercise within their normal daily routine, where mobility is not a problem.

Although technically possible it would probably require a fenestrated or cuffless tube in situ so that the patient could breathe via the mouth. This would potentially reduce the resistance to airflow and hence allow for a more realistic exercise performance. How safe it would be, particularly blocking off the tube to only allow nasal-oral or oral breathing may need some careful consideration beforehand.

Attempting to breathe via the cuffed tracheostomy tube would cause significant dyspnoea as the resistance to airflow, through the narrowed tube would be significant and would increase with increasing levels of ventilation – see equations 1 – 3 and work through these!

Unless it is essential to measure ventilation and VO2 then realistically this test, even using a cycle ergometer may prove just too complex to undertake, and the complexity of understanding how the revised airway would affect the perception of dyspnoea and hence the actual level of exercise achieved would also be challenging. On a treadmill, this may be even more fun! However, this is a challenge yet to be presented and undertaken, and one which some of us would be willing to consider!

6-Minute Walk Tests

It may be more realistic to undertake this type of test in the mobile patient, measuring heart rate and O_2 saturation using pulse oximetry with a standard protocol. This would at least provide information on O_2 desaturation and BORG scores, but is not as aesthetically pleasing as a CPET test.

Other Tests

The tests outlined above present a range of challenges, but none are technically impossible. There are other tests that may be required or may be useful in some patients, and these should not be excluded from the assessment of patients. These tests may include bronchial challenge testing, lung clearance index, ventilatory drive studies, or invasive lung mechanics studies. Within the scope of this review, I have not gone into any detail of these and other possible tests as not every laboratory will be able to undertake these routinely.

Conclusion

Patients with a tracheostomy or a laryngectomy present a challenge to lung function testing laboratories, but this challenge is not insurmountable and should not be regarded as anything different from any other complex patient referred to the laboratory, and who requires assessment. This applies both to children and adults. The author, has over the years, undertaken most of the tests outlined above – with the exception of CPET testing, without undue difficulty. The key is careful preparation, working with the patient and in children, with the family as well, to ensure the required seal is achieved and then understanding how the changed upper airway geometry may influence the interpretation of the obtained results are all that are required – Simples!

References

1. Kendrick AH. Lung function testing in tracheostomy and laryngectomy patients. Inspire 2014; 15: 14 – 28.
2. Heyden R. The respiratory function of laryngectomized patients. Acta Otolaryngol (Suppl) 1950; 85: 39 – 59.
3. Fourage M. Étude des problèmes respiratoires avant et après laryngectomie. Acta Otorhinolaryngol Belg 1964; 18: 579 – 600.
4. Torjussen W. Airway obstructions in laryngectomized patients. A spirometric investigation. Acta Otolaryngol 1968; 66: 161 - 170.
5. Gaensler EA. Air velocity index; a numerical expression of the functionally effective portion of ventilation. Am Rev Tuberc 1950; 62: 17 – 28.
6. Pantazopoulos P, Corcondilas A, Antonakopoulos C, Yannakopoulos J, Coyas A. Remarques sur la fonction respiratoire avant et après laryngectomie totale. Ann oto-laryng (Paris) 1972 ; 89 : 253 – 256.
7. Harris S, Jonson B. Lung function before and after laryngectomy. Acta Otolaryngol 1974; 78: 287 - 94.
8. Wozniak S. Evaluation of dynamic compliance of lungs and disturbances of breathing mechanics in patients following laryngectomy for carcinoma of the larynx. Anaesth Resus Inten Therap 1975; 3: 43 – 55.
9. Usui N. Ventilatory function in laryngectomized patients. Auris Nasis Larynx 1979; 6: 87 – 96.
10. Klos A. Zachowanie sie czynnosci oddechowej pluc I wymiany gaszowej u chorych po calkowitym wycieciu krtani z powodu raka. Otolaryngol Pol 1979; 33: 673 - 674
11. Togawa K, Konno A, Hoshino T. A physiologic study on respiratory handicap of the laryngectomized. Ach Otorhinolaryngol 1980; 229: 69 – 79.
12. Todisco T, Maurizi M, Paludetti G, et al. Laryngeal cancer: long-term follow-up of respiratory functions after laryngectomy. Respiration 1984; 45: 303 - 315.
13. Brunetti F. Observations of the respiratory dynamic in laryngectomized patients. Acta oto-lar (Stockh) 1950; 38: 334 – 343.
14. Gregor RT, Hassman E. Respiratory function in post laryngectomy patients related to stomal size. Acta Otolaryngol (Stockh) 184; 97: 177 – 183.
15. Davidson RN, Hayward L, Pounsford JC, Saunders KB. Lung function and within-breath changes in resistance in patients who have had a laryngectomy. Q J Med 1986; 60: 753 - 762.
16. Hentona H, Ishikawa N, Takoda S. Change in the respiratory function after laryngectomy. Nihon Jibiinkoka Gakkai Kaiho. 1988; 91: 56 - 64.
17. Durán Cantolla J, Sampedro Alvarez JR, Zurbano Goñi F, et al. Measurement of pulmonary function in laryngectomized patients. An Otorhinolaringol Ibero Am 1989; 16: 387 - 400.
18. Gardner WN, Meah MS. Respiration during exercise in conscious laryngectomized humans. J Appl Physiol

1989; 66: 2071 - 2078.

19. Misiolek M, Ziora D, Oklek K, Namyslowski G. Evaluation of upper airway obstruction after partial laryngectomies by radiological method and flow-volume loop analysis. J Laryngol Oto 1994; 108: 954 – 956.

20. Miller MR, Hyatt RE. Evaluation of obstructed lesions of the trachea and larynx by flow-volume loops. Am Rev Respir Dis1973; 108: 475 – 481

21. Matsuura K, Ebihara S, Yoshizumi T, et al. Changes in respiratory function before and after laryngectomy. Nippon Jibiinkoka Gakkai Kaiho. 1995; 98: 1097 - 1103.

22. Ackerstaff AH, Hilgers FJ, Balm AJ, et al. Long-term pulmonary function after total laryngectomy. Clin Otolaryngol Allied Sci 1995; 20: 547 - 551.

23. Hess MM, Schwenk RA, Frank W, et al. Pulmonary function after total laryngectomy. Laryngoscope 1999; 109: 988 - 994.

24. Matyia G. Objective evaluation of respiratory function of the larynx after partial laryngectomy of various range. Ann Acad Med Stetin 2001; 47: 145 – 161.

25. Tan AKW. Incentive spirometry for tracheostomy and laryngectomy patients. J Otolaryngol 1995; 24: 1995

26. Goldstein GH, Lloreta AM, Ojo B, Malkin BD. Incentive spirometry for the tracheostomy patient. Otolaryngol – Head & Neck, Surg 2012; 147: 1065 – 1068.

27. Moodie L, Reeve J, Elkins M. Inspiratory muscle training increases inspiratory muscle strength in patients weaning from mechanical ventilation: a systematic review. J Physiotherapy 2011; 57: 213 – 221.

28. Condessa RL, Brauner JS, Saul AL, Baptista M, Silva ACT, Vieira SRR. Inspiratory muscle training did not accelerate weaning from mechanical ventilation but did improve tidal volume and maximal respiratory pressures; a randomized trial. J Physiotherapy 2013; 59: 101 – 107.

29. Vázquez de la Iglesia F, Fernádez González S. Method for the study of pulmonary function in laryngectomized patients. Acta Otorrinolaringol Esp 2006; 57: 275 – 278

30. Castro MA, Dedivitis RA, Macedo AG. Evaluation of a method for assessing pulmonary function in larygegectomees. Acta Otohimolaryngol Ital 2001; 31: 243 – 247.

31. Ackerstaff AH, Souren T, van Zandwijk N, Balm AJM, Hilgers FJM. Improvements in the assessment of pulmonary function in laryngectomized patients. Laryngoscope 1993; 103: 1391 – 1394.

32. Nakhla V. A homemade modification of a spacer device for delivery of bronchodilator or steroid therapy in patients with tracheostomies. J Laryngol Otol 1997; 111: 363 – 365.

33. Parkes SN, Bersten AD. Aerosol kinetics and bronchodilator efficacy during continuous positive airway pressure delivered by face mask. Thorax 1997; 52: 171 – 175.

34. Mirza S, Hopkinson L, Malik TH, Willatt DJ. The use of inhalers in patients with tracheal stomas or tracheostomy tubes. J Laryngol Otol 1999; 113: 762 – 764.

35. Piccuito CM, Hess DR. Albuterol delivery via a tracheostomy tube. Respir Care 2005; 50; 1071 – 1076.

36. MacIntyre NR. Aerosol delivery through an artificial airway. Respir Care 2002; 47: 1279 – 1285.

37. Berlinski A, Chavez A. Albuterol delivery via metered dose inhaler in a spontaneously breathing pediatric tracheostomy model. Pediatr Pulmonol 2013; 48: 1026 – 1034.

38. Newhouse MT. Hemoptysis due to MDI therapy in a patient with permanent

tracheostomy: treatment with mask AeroChamber. Chest 1999; 115: 279 – 282.

39. Hughes JM, Saez J. Effects of nebulizer mode and position in a mechanical ventilator circuit on dose efficiency. Respir Care 1987; 32: 1131 - 1135.

40. O'Riordan TG, Greco MJ, Perry RJ, Smaldone GC. Nebulizer function during mechanical ventilation. Am Rev Respir Dis 1992; 145: 1117 - 1122.

41. O'Doherty MJ, Thomas SH, Page CJ, Treacher DF, Nunan TO. Delivery of a nebulized aerosol to a lung model during mechanical ventilation. Effect of ventilator settings and nebulizer type, position, and volume of fill. Am Rev Respir Dis 1992; 146: 383 - 388.

42. Quinn WW. Effect of a new nebulizer position on aerosol delivery during mechanical ventilation: a bench study. Respir Care 1992; 37: 423 - 431.

43. Ari A, Areabi H, Fink JB. Evaluation of aerosol generator devices at 3 locations in humidified and non-humidified circuits during adult mechanical ventilation. Respir Care 2010; 55: 837 - 844.

44. Ari A, Atalay OT, Harwood R, Sheard MM, Aljamhan EA, Fink JB. Influence of nebulizer type, position, and bias flow on aerosol drug delivery in simulated pediatric and adult lung models during mechanical ventilation. Respir Care 2010; 55: 845 - 851.

45. Willis LD, Berlinski A. Survey of aerosol delivery techniques to spontaneously breathing tracheostomized children. Respir Care 2012; 57: 1234 – 1241.

46. Amirav I, Newhouse MT. Aerosol delivery in tracheostomized children: Time for Guidelines! Respir Care 2012; 57: 1350.

47. American Association of Respiratory Care. Clinical practice guideline. Selection of an aerosol delivery device for neonatal and pediatric patients. Respir Care 1995; 40: 1325 - 1335.

48. Berlinski A, Willis JR. Albuterol delivery by 4 different nebulizers placed on 4 different positions in a pediatric ventilator In Vitro model. Respir Care 2013; 58: 1124 – 1133.

49. Pitance L, Vecellio L, Delval G, Reychler H, Liistro G. Aerosol delivery through tracheostomy tubes: an In Vitro study. J Aerosol Med Pulm Drug Deliv 2013; 26: 76 – 83.

50. Berlinski A. Nebulized Albuterol delivery in a model of spontaneously breathing children with tracheostomy. Respir Care 2013; 58: 2076 – 2086.

51. Johnson DC. Interfaces to connect the Handihaler and Aerolizer powder inhalers to a tracheostomy tube. Respir Care 2007; 52: 166 – 170.

52. MacIntyre N, Crapo RO, Viegi G, et al. Standardisation of the single-breath determination of carbon monoxide uptake in the lung. Eur Respir J 2005; 26: 720 – 735.

53. Brewer LM, Orr JA, Pace NL. Anatomic dead space cannot be predicted by body weight. Respir Care 2008; 53: 885 – 891.

54. Numa AH, Newth CJ. Anatomic dead space in infants and children. J Appl Physiol 1996; 80: 1485 – 1489.

55. Iida-Kondo C, Yoshino N, Kurabayashi T, et al. Comparison of tongue volume/oral cavity volume ratio between obstructive sleep apnea syndrome patients and normal adults using magnetic resonance imaging. J Med Dent Sci 2006; 53: 119 – 126.

56. Weibel ER. Morphometry of the Human Lung. 1963. Berlin; Springer-Verlag.

57. Wanger J, Clausen JL, Coates A, et al. Standardisation of the measurement of lung volumes. Eur Respir J 2005; 26: 511 – 522

58. Vicencio AG, Bent J, et al. Management of severe tracheal stenosis using flexible bronchoscopy and impulse oscillometry. J Bronchology Interv Pulmonol 2010; 17: 162 – 164.

59. Handa H, Huang J et al. Assessment of central airway obstruction using impulse oscillometry before and after interventional bronchoscopy. Respir Care 2014; 59: 231 – 240.

60. Kuhnle GE, Brandt T, et al. Measurements of respiratory impedance by oscillometry – effects of endotracheal tubes. Res Exp Med (Berl) 2000; 200: 17 - 26.

61. British Thoracic Society. Managing passengers with stable respiratory disease planning air travel: British Thoracic Society recommendations. Thorax 2011; 66: Supplement 1.

62. Kendrick AH, Johns DP, Leeming JP. Infection control of lung function equipment: a practical approach. Respir Med 2003; 97; 1163 – 1179.

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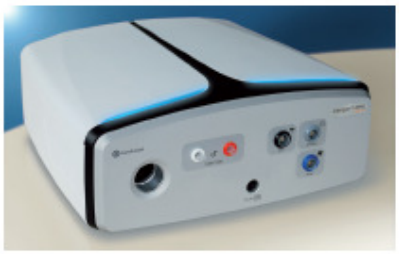

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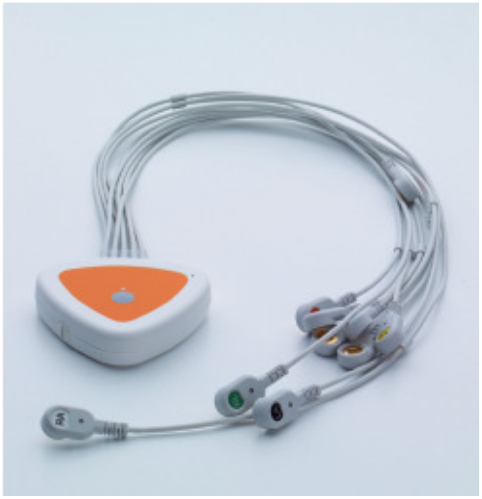

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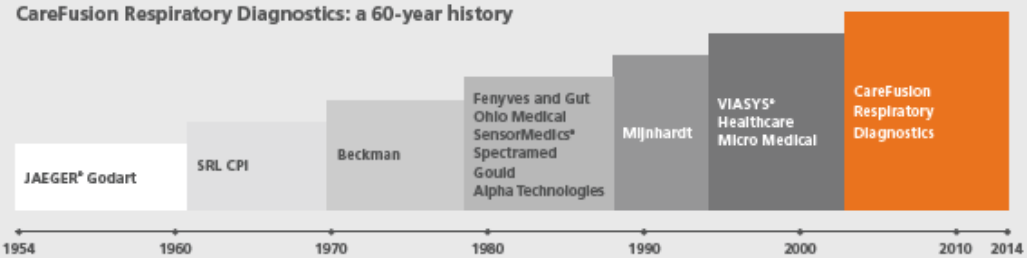

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