



Inspire

The Official Journal of The Association of Respiratory Technicians and Physiologists
Vol 2 No. 2 January 1999

Reg. Charity No. 2900907

FIRST WORD

In order to communicate a number of important developments concerning technical / scientific grading structures, future training and departmental structures we have produced this additional issue of Inspire. These topics, which concern the future of the profession, will be discussed at the January Meeting of the ARTP. We urge you to read carefully the briefing from Sue Hill concerning a number of DOH initiatives which could profoundly affect your career and livelihood. If you are unable to attend our winter meeting in Doncaster, but wish to express a view please write to me at Inspire. Additionally if you have a question or comment that you would like raised at the meeting please let me know and I will forward your views.

The next issue of Inspire will not appear until Spring 1999, and for the summer edition hopefully we will be back on track with an issue in August / September. We need articles from YOU. Please keep your letters, comments and articles rolling in to INSPIRE. It is important to keep our communication channels open and busy so that the ARTP can be responsive and pro-active in your interests. Please let me know your concerns about the future of respiratory function in the ever changing NHS. Additionally we are always open to ideas and suggestions concerning practice, developments, training and gradings. Write to me:

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Glenfield Hospital
Leicester LE3 9QP

ARTP/BTS NATIONAL ASSESSMENT 1999

REGISTRATION IS CURRENTLY TAKING PLACE

FURTHER DETAILS AND AN APPLICATION FORM MAY BE OBTAINED FROM:-

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CLOSING DATE FOR THE RECEIPT OF APPLICATIONS IS

FRIDAY 26TH FEBRUARY 1999

• WANTED • OHIO SPIROMETER

Contact: Andrew Robson

Tel: 0131 537 2575

Dates for your Diary

21-23 January 1999

ARTP Winter Meeting

Doncaster Racecourse

19th-23rd April 1999

Short Course in Advanced Respiratory Physiology

Coventry University

19th-23rd April 1999

1-2 July 1999

BTS Summer Meeting

(including the BTS/ARTP joint symposium)

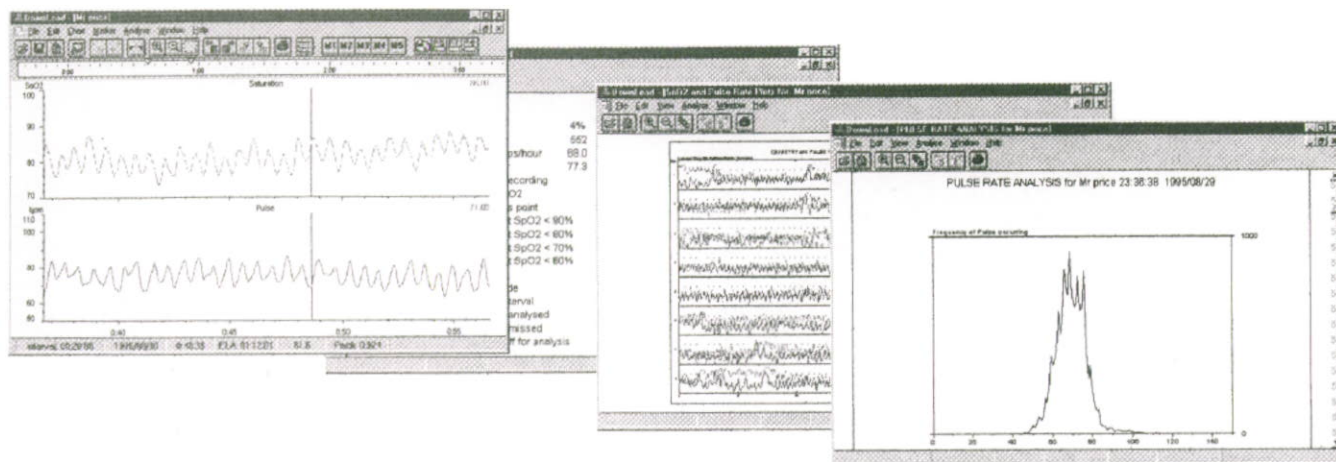
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See page 12 for more details

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Contact:

Sue Revill (Editor)
Fax only: 0116 258 3950

CHARITY NEWS

NATIONAL ASTHMA CAMPAIGN

London H/Q tel no for enquiries or leaflets
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The Asthma Agenda is the latest publication from the NAC. It can be found on the charity's web site at <http://www.asthma.org.uk>.

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METHACHOLINE CHALLENGE TESTING

Joanna Harrison & Jodie Carter

LUNG INVESTIGATION UNIT, DEPT. OF RESPIRATORY MEDICINE, QUEEN ELIZABETH HOSPITAL, BIRMINGHAM

Background information

Bronchial hyperreactivity is a non-specific tendency of the smooth muscle of the tracheobronchial tree, to contract to an excessive degree in response to a variety of stimuli. The response of the airways to exogenous stimulation may be quantified in the lab by bronchial provocation testing using aerosols of histamine, methacholine or any other inhaled agonist, in progressively increasing doses, that stimulates bronchoconstriction in a dose dependent manner. There are two types of bronchial challenge testing; specific and non-specific. Non-specific is used for detecting presence or absence of bronchial hyperreactivity and specific is used to identify what particular agent is causing bronchoconstriction. Bronchial challenge testing is performed in order to rule in or out bronchial asthma in patients with unexplained cough, dyspnoea, wheeze and chest tightness. It can be used to objectively confirm previously unconfirmed diagnosis of asthma in patients with atypical symptoms. In known asthmatics it gives an objective measure of severity and follows the effects of treatment. This was shown by Ryan G et al¹ who demonstrated that challenge testing compares favourably to diurnal variation in Peak Expiratory Flow (PEF).

Considerations

Bronchoconstriction can be measured by looking at acute changes in Forced Expiratory Volume in one second (FEV₁) or Specific Airway Conductance (sGaw). Melvin R² found that FEV₁ is a more discriminating measurement than sGaw whilst virtually no normal individual will decrease their FEV₁ by 20% or more, a significant number of normal subjects will increase their sGaw by 35% or more. For example, patients with allergic rhinitis or hayfever. Therefore, FEV₁ has been found to be a more specific measurement, requires less expensive equipment and experiences less variation of repeated measurements.

Delivery of drug

The way in which the aerosol, for the bronchial challenge test, is produced and inhaled may influence the results.

The physical characteristics of the aerosol generation system, pattern of breathing and the airway characteristics are important factors determining the dose and distribution of aerosol to the lung.

Ryan et al³ compared dosimeter delivery plus deep inhalation with continuous nebulisation plus tidal breathing for histamine challenge testing. They found no major differences in the measurement of bronchial reactivity although aerosol deposition was shown to be more central with the dosimeter and deep inhalation method.

With continuous nebulisation, the aerosol is delivered throughout inhalation and therefore aerosol nebulised towards the end of inspiration will be deposited in the main airways or exhaled. This can account for 20% of the drug. In contrast, Nieminen, M.M et al⁴ found that the dosimeter technique reduces the exhaled loss of aerosol to 1-2% of the nebulised solution. Thus the dosimeter is favoured.

Choice of agent

There are two bronchoprovocation agents currently used for the performance of non-specific challenge tests:

Methacholine is a parasympathomimetic synthetic analogue of acetyl choline. It stimulates muscarinic and post ganglionic parasympathetic receptors resulting in smooth muscle contraction in the airways. Bronchoconstriction is rapid and peaks within 1-4 minutes and lasts for approximately 75 minutes. It is almost always promptly reversed by inhalation of β -adrenergic agonists. It is commercially available as a powder and when it is reconstituted with physiologic saline it remains stable at room temperature or refrigerated for four months.

Histamine is a naturally occurring chemical and stimulates smooth muscle H1 receptors causing contraction. When inhaled in concentrations of 10mg/ml or more, headache, sore throat and flushing is common. It reaches a peak in 1-2 minutes and is maintained for 17

minutes. As there is a greater risk of side effects when using the inhaled histamine, methacholine is the preferable agent.

Contraindications

These include severe airflow obstruction (FEV₁ less than 1.2L), recent myocardial infarction (MI), stroke, aneurysm and an inability to understand the procedure. Relative contraindications include spirometry induced airflow obstruction, moderate-severe airflow obstruction (FEV₁ 1.2-1.5L), upper respiratory tract infections, exacerbation of asthma, hypertension, pregnancy and epilepsy requiring drug treatment.

Essential equipment and materials

- Spirometer, for the performance of FEV₁
- Dosimeter with source of compressed air at 50psi and nebuliser for the delivery of methacholine.
- Full Resuscitation equipment
- Measuring scales for calibration of dosimeter output (accurate to 0.01 grams)
- Acetyl- β -Methyl Choline Chloride (methacholine) and normal saline
NB: There can be some problems in obtaining methacholine, however it can be purchased ready diluted from Nova Laboratories LTD, Martin House, Gloucester Crescent, Wigston, LE184YL.
- 3ml syringe with needle for dilution purposes
- β_2 Adrenergic agonist nebule (2.5mg) plus 2ml 0.9% sodium chloride (made up in nebuliser)

Procedure

Medication taken for asthma or hayfever inhibit the response of the airways to histamine and methacholine and should therefore be withheld for their duration of action before any test. Inhaled steroids, oral steroids and sodium cromoglycate may alter airway responsiveness but they do not acutely alter the response of the airways to histamine or methacholine. As a result their use should not be discontinued prior to testing.

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- 1) Current drug therapy should be recorded, including the daily dose and the time of the last dose of inhaled or oral bronchodilatory therapy.
- 2) The patient should be clearly informed of the test procedure and that it may result in wheeze or chest tightness, and that a bronchodilator is available for immediate reversal of symptoms.
- 3) Measure a baseline FEV₁ and VC at least three times or until reproducible within 5%. Calculate the mean baseline FEV₁ from the three stable values. If airway hyperresponsiveness is observed, the best FEV₁ should be reported with a comment relevant to the instability of the baseline.
- 4) If the FEV₁ (BTPS) is less than 1.5 litres the technician should not proceed with the test until the referring physicians consent is obtained. A test should never commence when the measured FEV₁ is less than 1.2 litres.
- 5) The first aerosol delivered is the diluent which acts as a control. Three millilitres of diluent is placed within the nebuliser vial and attached to the dosimeter. A nosepeg is placed on the patient and they are instructed to take five relaxed inhalations from the mouthpiece. The inhalations should be from residual volume (RV) to total lung capacity (TLC).
- 6) After the fifth inhalation the clock is started. The FEV₁ is then measured at 30 and 90 seconds. If the measurement at 90 seconds is the same or lower than at 30, the FEV₁ should be repeated at 3 minutes (to avoid tiring the patient the FEV₁ should only be measured once on each occasion).
- 7) If the FEV₁ falls by more than 20% from the baseline FEV₁ or to less than 1 litre, no further inhalations are given.
- 8) If the decrease in FEV₁ is less than 20%, the first dose of methacholine is given. The concentrations of methacholine are given at 5 minute intervals and are as follows: 0.03, 0.06, 0.125, 0.50, 1.00, 2.00, 4.00, 8.00, 16.00mg/ml.

- 9) Repeat steps 5-8 with increasing concentrations of methacholine until the FEV₁ has fallen by 20% from the baseline, the FEV₁ is less than 1.5 litres or the highest concentration has been given.
- 10) Once the FEV₁ ceases falling after the last inhalation, the patient is given 2.5mg of nebulised terbutaline/salbutamol. The FEV₁ is recorded after a ten minute interval and should measure similar to pre-challenge values.

Calculation of results

The percent fall in FEV₁ is calculated as follows:

$$\frac{\text{Mean baseline FEV}_1 - \text{Lowest FEV}_1 \text{ post methacholine}}{\text{Mean baseline FEV}_1} \times 100$$

Expression of results

Reactivity can be expressed in terms of the concentration of agent required to reduce the FEV₁ by 20% (PC₂₀). However, it is more useful to express the results in terms of the dose of agent required to provoke a fall in FEV₁ of 20% (PD₂₀). This enables comparison of results between different centres where different outputs and nebulisers are used.

Reporting results

Increased responsiveness to concentrations below 0.25mg/ml is classed as severe, between 0.25mg/ml and 2mg/ml is classed as moderate and between 2mg/ml and 4mg/ml is mild. When the PC₂₀ is between 2mg/ml and 16mg/ml current symptoms due to asthma are likely to be mild, infrequent or absent.

The results obtained from the investigation should be recorded on a report form which includes patient details, predicted FEV₁, baseline and lowest measured FEV₁ post provoking concentration and the PD₂₀. A dose response curve on a semi-logged scale should be included as part of the report which plots the % change in FEV₁ against the cumulative concentration of the provocative agent.

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NEWS from the Executive Committee

With the BTS/ARTP Summer (what summer?) meeting in Edinburgh a distant memory, the next dates for your diary are:

The BTS Winter meeting in London 2-4 December
The ARTP Winter meeting in Doncaster 21-23 January

The provisional programme and registration form should be sitting on your desk now and after the success of the 25th Anniversary Conference it will be on a 'first come, first served' basis so get your forms in soon to avoid disappointment.

Preparations are already underway for the ARTP/BTS symposium for the summer meeting 1999. This symposium will be on the Role and Assessment of bronchial responsiveness and the draft agenda has been assembled.

The changes to the ARTP Constitution are now in their final draft (hopefully!) and will be circulated before the Winter meeting for comment and final approval. A resolution of the name change conundrum may be close with the suggestion of... ARTP! The letters are the same but the name now reads 'Association for Respiratory Physiology and Technology' - the approval of the membership will be sought when the updated constitution is launched.

The Executive Committee has also been working hard on formatting a Code of Conduct and Disciplinary Code for the ARTP. A draft copy for approval should be ready at the beginning of next year (workloads permitting!).

As you are aware, there have been one or two changes to the Executive Committee since the last update. Following Dr Roger Carter's resignation in the summer, Jane Benson agreed to act as secretary until the next AGM when the post will be up for re-election. There has been an addition to the committee with the election of Gill Butcher from Burton Hospitals. Good luck Gill.

The financial picture continues to look very healthy with an ever increasing number of job adverts - does this mean that more of us are leaving or more new posts are being created?

There are several bursaries available from the ARTP funds and manufacturers sponsorship. These can be used to attend National and International meetings so contact Jane Benson at Rotherham to get your hands on the cash.

The ARTP has been approached by a number of manufacturers and drug companies for input on establishing joint training initiatives. This may take the form of specialist training centres with appropriate funding received for information and involvement. We will give you more details when plans are finalised.

Order forms have been sent out for the Respiratory Handbook. Don't worry if you haven't received yours yet - there have been some problems with the printers but these should be resolved shortly.

There has been much talk on Occupational Standards and State Registration in recent months. Dr Hill has included a more detailed explanation of these in her article in this issue of Inspire. She will also be presenting an overview of the implications and complications of State Registration at the Winter meeting in Doncaster.

Another topic that will be covered in more detail at Doncaster is the proposed National Assessment in Spirometry. This has been approved by the ARTP/BTS Liaison Committee and is awaiting approval from the BTS Education Committee before its launch next year.

News from Europe indicates that the European Discussion Group Forum is provisionally planning its first meeting for September 1999. Definite topics for discussion have not yet been decided but more information will be available later next year - it seems that 1999 will be busier than ever. The re-vamped buyers guide is proceeding to plan and has a publication date in Spring 1999 - a European version of 'What' Spirometer?

A new award for services to Respiratory Physiology has been proposed. Nominations will be suggested by members for consideration by the Committee and presented at ARTP meetings. The first award will be nominated by the Executive Committee for presentation at the Winter meeting in Doncaster.

Get your thinking caps on for further worthy nominees.

And finally, congratulations to Dr Duncan Hutchison who has been awarded ARTP life membership for his outstanding support of the ARTP in often difficult times. We hope to see him at Doncaster.

Professional Issue Update

Dr Sue Hill, Queen Elizabeth Hospital, Birmingham

At the forthcoming Winter Meeting a session has been devoted to professional issues since after many years of what may appear to be stagnation, the scientific and technological workforce is high on the agenda at both the Department of Health and NHS Executive. It is recognised that there is need for a clearly defined and consolidated scientific and technological workforce in a new era of health care provision and delivery where Clinical Governance will be an integral part.

Of importance is the vital contribution that all groups under the clinical physiology banner, including respiratory physiology, has been clearly recognised and not overshadowed by the larger staff groups within the scientific and technological workforce. This report will briefly outline some of the important groups and projects and is designed to bring you up to date. Please feel free to write to me on any point for further clarification and information. We will of course be providing further details during the session at the Winter Meeting where Dr Peter Greenaway will also be speaking on the important role that all staff groups under the scientific/technological banner could and are playing in research and development activities and Jocelyn Germain, the President of the Institute of Biomedical Sciences will be talking about what it is like to be a state registered professional group.

National Advisory Group for Scientists and Technologists in the NHS (NAGST)

This group was formed in 1998 to replace the old ACCESS group which specifically dealt with the commissioning of Grade A clinical scientist training placements in a variety of disciplines (not Respiratory Physiology) and was predominantly composed of regional training officers.

The new group was renamed to reflect its coverage of both scientists and technologists in the workforce and has formal reporting responsibility to the Human Resource Directorate of the NHS Executive with four key purposes:-

a. To provide a national focus,

strategic oversight and specialist advice for the workforce planning and education and training requirements of scientific and technologist staff.

- b. To advise the NHS Executive Director of Human Resources, and thereby the Executive Board, on the workforce and education policy implications for the scientific and technologist staff groups.
- c. To provide a national co-ordination mechanisms for local workforce planning and education commissioning for the scientific and technologist staff groups and to contribute to the NHS Executive's Planning and priorities guidance.
- d. To provide advice and support to the Regional Education Development Groups in the assessment of the educational purchasing plans of "lead" consortia so that the future supply of fully trained and competent scientists and technologists for the NHS can be assured.

These four key purposes are achieved through a number of key objectives which includes developing quality assurance frameworks and establishing links with relevant professional bodies to ensure a shared understanding of education and training issues

The group has no official professional body representation although three practitioners (1 Biochemist, 1 Medical Physicist and myself) are members in a regional capacity. The other members are representatives of the NHSE, regional education development groups and lead training consortia, the Welsh, Scottish and Northern Ireland Offices and the Department of Health (Chief Scientific Officer).

To date, three meetings have been held which have concentrated on developing the remit and identifying key issues. The lack of inclusion of many groups apart from clinical scientists in well established disciplines (not respiratory physiology) in the non-medical, education and training (NMET) levy to provide national top-sliced funding for education and training purposes has been particularly highlighted.

This group will serve as the main advisory body to the NHSE on all aspects of this sector of the workforce and has already received the EVETSIN project (see later) and devised a recommended implementation strategy for the NHSE. The occupational standards feasibility study report (see later) will also be received by this group to devise recommendations for implementation by NHSE.

To begin to develop links with professional bodies a meeting with NAGST is currently being arranged for February where the ARTP will be formally represented by Brendan Cooper. It is important to note however that the multiplicity of professional bodies in the sector is seen as a problem and membership of overarching bodies is actively encouraged to streamline the process but not to down-regulate the requirements of individual groups. NAGST is therefore going to play a key role in the future development of the scientists and technologists in the NHS workforce and has a direct link to key decision makers.

EVETSIN PROJECT

In 1995 the Department of Health / NHS Executive commissioned a study into the postgraduate education and training of some science graduates within the NHS. This study was particularly looking at the vocational training of science graduates entering the life sciences / pathology specialities (MLSO's and Clinical Scientists - in some disciplines), physical sciences (Medical Physicists and MTO's in Rehabilitation Engineering) and clinical physiology (Clinical scientists in Audiology and MTO's in Cardiology). This study reported in the Autumn 1998 and identified a number of issues which have relevance to clinical scientists, MLSO's and MTO's in all disciplines and not just those groups included in the study or only science graduates. Many of the findings from this study were also supported by findings in the occupational standards feasibility project. Currently the report is being considered by NAGST and an implementation strategy is being

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developed for the NHS Executive (NB I have been sitting on the implementation strategy sub-committee and will update you when information is in the public domain). Some of the areas highlighted in the EVETSIN project include the need for clear learning outcomes and training plans for vocational training, robust systems for assessing competence (a key area for state registration purposes), clarity of pathways of transfer between professional groups (for example from MLSO/MTO grades to clinical scientist grades and vice versa) and a complete reappraisal of the MTO education and training structure to reflect the work function undertaken. It is recognised throughout the report the valuable role that professional bodies do and can play in setting and maintaining standards of excellence and competence to practice.

OCCUPATIONAL STANDARDS FEASIBILITY PROJECT

This project commenced in April 1998, commissioned and funded by the Department of Health / NHS Executive and was completed within 6 months. The final report was submitted to the Project Steering Committee in December 1998 and will be considered by the NAGST group early in the New Year.

The project was initiated following observations by the Department of Health / NHSE that scientific and technological staff within the NHS form a heterogeneous and fragmented sector performing a wide range of functions and duties. Different staff groups having different levels of formality and clarity in their education and training requirements, different degrees of professional regulation and different career pathways with no consistency in adherence to Whitley Council terms and conditions. The NHS of the future, however, will require scientists and technologists trained and skilled "fit for purpose" who will have a crucial role to play within modern evidence based medicine.

Occupational standards (OS) define benchmarks for national good practice by clearly outlining key components of education and training to achieve competence. It was felt that OS could offer a mechanism for clarifying commonalities and boundaries between constituent disciplines of the scientific and technological workforce

and the potential for partnership approaches to education and training. In the longterm, by now clearly defining what is required for competent performance, this could lead to consolidation of the workforce and a rationalisation of staff development and potentially enhanced career prospects.

The broad remit of the project was to explore the feasibility of developing an occupational standards framework in this area and to advise on whether it was possible given the complexity of the sector, suitable given the types of organisations involved and desirable as perceived by all the interested groups involved. The work was undertaken by a Consortium of four professional individuals to cover Life Sciences/Pathology (G. Beastall, Glasgow / J. Germain, London), Clinical Physiology / Physiological Measurement (myself) and Physical Sciences (Peter Griffiths, Lincoln). The Consortium was supported by two external consultants and advised by the Chief Scientific Officer.

An Occupational Map was developed which confirmed the heterogeneity of sector with over 50 different scientific and technological disciplines identified. The project identified a multiplicity of educational and training programmes in existence, ranging from no formal requirements to 4 years postgraduate training including requirements for higher degrees and professional qualifications to enable progression, with some groupings having established CPD schemes. State registration of the workforce being only well developed in some professional groupings (MLSO's) but viewed with enthusiasm by all other professional groups as a means of protecting the public and regulating practice.

A Functional Map was developed with the aid of the professional bodies to start to define the job roles and function undertaken. The key purpose to encapsulate the function of the sector was defined as "To direct and provide clinical, scientific and technological services for patient diagnosis, management and care", and was subdivided into 8 key areas to represent major components of work. From further defining it was possible to make explicit the functions performed by various disciplines within the sector, including in respiratory physiology laboratories. Overlap in function was evident in some areas demonstrating potential for a framework of occupational standards to be developed which

could include common standards which would be used by all for some functions.

A questionnaire to Senior Trust Managers reinforced the difficulty in identifying the sector and supported the development of occupational standards to ensure a competent and safe workforce. They clearly identified the need for any standards development to be endorsed by professional bodies.

The educational sector also gave support for clearly defined educational requirements to allow appropriate course, module and/or syllabus design for the scientific/technological workforce. The project therefore demonstrated that it is technically feasible to develop occupational standards and that the appraisal appears to be both suitable and desirable. The major recommendation from the feasibility study will be that a new project is commenced as soon as possible to include professional body representation and other key stakeholders and with in depth consultation within the NHS.

This has been a very exciting project to be involved with and throughout the vital role that staff in Clinical Physiology disciplines including respiratory physiology are playing has been highlighted. The project has generated much interest and will hopefully lead to better recognition, status and enhanced career prospects in the future as well as supporting state registration initiatives.

STATE REGISTRATION

There are many rumours circulating with regard to this important issue which are important to dispell and replace with the facts.

Currently any groups who are state registered fall under the Professions Supplementary to Medicine Act of 1960. This Act however was seen as out of date and in 1995/6 an independent team of consultants reviewed its content during which time they asked professional bodies, amongst others, to comment which both the ARTP (through myself) and the BTS did. Both societies presented a case for lung function staff to be included in any subsequent Act by the very nature of the work undertaken.

The eventual report (published in 1996) defined the principles that new legislation should follow and

recommended a new body with much greater flexibility and policy making power than the current Council for Professions Supplementary to Medicine (CPSM) has to regulate the workforce.

The report stated that the overall function of CPSM should be defined as:-

"providing protection to the public by specifying and monitoring standards of education, training and conduct for health professions"

The core elements of public protection and fitness to practice is generally accepted to require control over four main areas:

- i) Initial qualification / registration
- ii) Continuity competence / professional development
- iii) Standards and ethics
- iv) Discipline

One of the major scientist/ technological groupings that come under the current Act are the MLSO's. This group of staff now have an all graduate entry to the profession from science courses that have been approved by CPSM. They obtain state registration after a minimum of 1 year in service following a CPSM endorsed oral competence examination which is far reaching. Compliance with a CPD scheme is voluntary and a register is kept by the professional body. Furthermore, clearly defined educational requirements for progression through the career structure are laid down and generally accepted.

Several groups have attempted to gain state registration over the years and have failed because of the small numbers of staff involved. The review of the 1960 Act has certainly made it difficult for many other groups to be considered for inclusion until the new legislation is accepted and put into place. It is currently at the Privy Council and a decision could be made at any time dependent on Government priorities.

There are 3 vacancies within the existing CPSM system and many of you may have heard that Clinical Scientists are to be included. Indeed the application has received approval from CPSM for inclusion (together with the Ambulance Paramedics and Speech and language therapists) however things are far from agreed and require approval from many

quarters including the Privy Council itself.

Clinical scientists in the life sciences/pathology, audiology and physical sciences have well established education and training schemes including formal assessment of competence and fulfil many of the far reaching criteria for state registration. Some groups have also contributed to a voluntary register under the science registration council and this has helped the case for inclusion under the current Act.

The application for Clinical Scientists does not currently include those working in Respiratory Medicine / Physiology as all training/education routes are ad hoc at present. Clinical scientists in respiratory medicine / physiology are in a similar position to MTO grades, and the ARTP and BTS are working to establish education and training strategies that would be appropriate for state registration purposes for both groups of staff.

It is being made clear however that for MTO's in clinical physiological disciplines a case with others, in much the same way as has happened with clinical scientists and MLSO's, will carry much more weight than trying to go alone which is why we have been trying hard to establish the ground rules. Currently through a Department of Health Clinical Physiology forum which I helped to

establish with Peter Greenaway we are trying to find a cohesive way forward for state registration and other issues for all disciplines.

This may be through integration in to the Conference of Clinical Scientist Organisations, where we are already represented as a Clinical Physiology sub-section, is going to be proposed together with an overall change in the name to reflect Clinical Science in general rather than specific employment grades. I am waiting to meet under the auspices of the CCSO with the Science Registration Council to establish what we need to do to create an acceptable voluntary register and to begin to put the correct mechanisms in place.

Finally, I can assure you that clinical scientists in respiratory medicine / physiology are not in a different position to MTO's regarding state registration, for both groups of staff the details and infrastructure has to be established in line with the likely requirements of the new Act. We are trying to get clear guidance on how to proceed so that we can be ready to go if secondary legislation is put in place with possibly a directive to ensure the workforce is properly regulated as soon as possible. We will continue to keep you updated and informed throughout and continue to work on your behalf.

MEMBERSHIP UPDATE

Report from Steve Scholey

The total number of paid up members currently stands at 358.

Sadly we lost several members who for one reason or another have not renewed their membership. This is of great concern to us. At the last Executive meeting of the Association it was decided that we need to encourage more of the Respiratory workforce to become members of the ARTP. So if you know of colleagues who are not members please encourage them to contact me at the address below.

FEES:	FULL:	£25
	Student:	£15
	Corporate:	£45

The fees for departmental membership will be calculated on a sliding scale depending on the number of members in the department. Following requests from departmental members we are increasing the number of copies of INSPIRE sent out to departments, up to a total of 3 (depending on the number of members in the department).

**Enquiries to Steve Scholey, ARTP Membership Secretary,
Chest Unit, General Hospital, Pontefract, West Yorkshire, WF8 1PL.**

"ON THE BLOWER" – Manufacturers News

1. YEAR 2000

So the year 2000 rapidly approaches - the ARTP have already held a meeting "into the Millenium" - ahead of time as usual! So what's it all about then? The Julian calendar was adopted by Julius Caesar in 45 BC (nothing to do with me!) and was used throughout Europe until 1582 when Pope Gregory XIII decided to include an extra day every fourth year and called this a "leap" year (after the Old Norse *hlaupar* meaning "to jump" (mmmmmmh!). So the rule goes that splitting the year up into 365 days is O.K. but an average solar year is 365.24219878 days and so every fourth year adds an extra day. However, the idea of our year numbers is to mark the birth of Jesus Christ who it is now thought was born in 15BC. Does any of this make sense? Well not really no. You see each leap year should occur in every year number that is divisible by 4 except centennial years which are treated as non-leap years unless the number of the century is divisible by four. (Hello, anybody still awake out there?) However, it has been decided to override this rule and make 2000 a leap year!!

OK, so does it all matter? Well yes, because a bunch of idle computer nerds in the 1970's and 1980's wrote programs using only the last two numbers of the year - thus sowing the seed of development of the Millenium Bug. Yet another great cock-up in the history of computing! The government and the NHS have deemed that we tackle the Millenium Bug in an ordered and structured manner. Result: NHS Trusts the length and breadth of the country are spending thousands of person-hours checking equipment compatibility, running tests and contacting manufacturers individually to confirm compatability. Duplication everywhere!. Didn't anyone think to ask the ARTP and other professional bodies to contact manufacturers for the information and publish lists of compatible respiratory equipment for hospitals to check? Answer: No!

Well this issue of On the Blower should be of interest to those of you unable to get to the ERS in Geneva. The exhibition area was a decent size with over 110 companies showing off equipment or drugs, etc.

2. TRADE STAND

General

Rumour-mongering and un-professional practice - time to clean up the market?

I'm sure that all of you, as well as me have been repulsed by the unprofessional "bickering and sniping" which has recently become a feature of some sales personel (and managers) particularly in the large lung function kit sector of the market. Particularly distastful is the malicious spreading of rumours about companies about to "go under" or be taken over or to withdraw from the market, etc. Whilst occassionally there is some sort of evidence to substantiate such rumours, generally they are unhelpful and misleading to customers. I am asking all the lung function associated manufacturers to agree to adopting our proposed ethical code of conduct when dealing with ARTP members (and non-members). The code is included as an appendix to this article.

Pharmaceuticals

Medeva Pharma have followed the launch of salbutamol

(Asmasal) in Clickhaler form, with a Clickhaler for inhaled steroids launched as **Asmabec Clickhaler** in three strengths 50mcg, 100mcg and 250mcg beclomethasone - each colour-coded for dose. Prices are £7.18 (200 doses), £10.55 (200 doses) and £13.24 (100 doses) respectively.

Lung function equipment

Sensor Medics have upgraded their software for body box and VMax 229. This appears to be very user friendly and incorporates a very powerful database which can allegedly import data from previous Sensor Medics software. **Sensor Medics** now offer a NO measurement system (VmaxNO) which is targeted at early detection of inflammatory processes in the lung. The popularity of this technique is growing, but whether it becomes a widely used clinical tool remains to be seen. **Sensor Medics** can also offer an oscillometry system (ROS), which at the moment is "stand alone" but I suspect will be an option on their full-testing systems. I don't have prices yet, but they won't be available in Europe until 1999. When will this technique be widely adopted by all manufacturers?

Also on the SensorMedics stand was the **EccoVision** Pharyngometer which uses acoustic technology to assess the cross-sectional area of the upper airway and oral cavity. This novel device appears to have potential clinical usefulness. They claim that this can be used to detect the potential sites of sleep-related upper-airway obstruction. The EccoVision can allegedly then be used to show the benefits of mandibular advancement appliances. The price for the UK is not set yet but the retail in the US for around \$9000, complete with hardware and fancy software. A little pricey considering their clinical usefulness is not yet fully determined!

MicroMedical launched their new spirometer the SuperSpiro which is a neat little desk-top device with printout facility and smart screen. I have been unable to get further details before going to press.

I have received literature on two respiratory muscle training devices now widely available. Whilst these have a use with rehabilitation programmes it appears that manufacturers are targeting Sports Medicine and the sporting world primarily. The **DeVilbiss RT Sport** (sounds like a new Japanese sportscar!) looks like a large banana (- except that it isn't yellow, you can't peel it and it tastes awful!). This trainer helps athletes and has been used to improve performance of the Welsh National Rugby Team (and God knows they need improvement!! Come back JJ & JPR Williams!!). The system comes with handset, base station and PC software at a list price of £1500 from DeVilbiss (Tel: 01384 446541).

The **Powerbreathe** from **IMT Technologies** (Tel: 0121 414 7676) doesn't look like a banana, and doesn't have any software or verification system but is listed at £45.00. It is actually aimed at the individual sportsperson - although there is no reason why they can't be bought for a rehabilitation programme. You pay your money.....!

The succesful **One-Flow** spirometer sold by Ferraris in the UK is to have a sister machine which measures FVC as well. Will this be called the Two-Flow or the One-Flow Plus??? I have had a trial of the original device and in

Continued on Page 10

short I would say it is a truly portable, easy for patients to use, simple to download spirometer. Although I had some initial niggles with installing the software and needing to acquire the correct cables to link to a PC (irritating oversight by the manufacturers), once the software was installed, analysis was simple, practical and logical. It would be an excellent device for occupational health studies, and nebuliser or other therapy trails in asthma. I have not undertaken any detailed validation checks, but initial assessment suggests it is both accurate and reliable..

I viewed the **Ferraris** stand at Geneva (I also viewed the Ferrari standing in the Geneva Motor Museum, but that's a different story!) and was disappointed to learn that the promised software for the Collins based system - is apparently behind schedule and won't be ready for 8-9 months!! This is not the message Executive Committee members were given in the early summer. Haven't I heard this somewhere before?

Chiron Diagnostics who are particularly famous for buying out Ciba-Corning the blood gas machine people have themselves been gobbled up by Bayer AG the drug company which has world revenues at an estimated \$2Bn. The story is that it will be "business as usual" for the moment when the "definitive agreement" is ratified by US and European regulatory bodies.

The ARTP has been in discussion with **Jaeger UK** to advise on their setting up their Jaeger Quality Management which involves "black-box" calibration and quality control devices. This is an exciting innovation which ARTP support and we hope other companies will follow suit and set up similar networks of quality control to raise national standards in lung function measurement.

I was interested to see **MediSoft** from Belgium selling a Negative Expiratory Pressure (NEP) system which can be used to measure the degree of limitation of expiratory flow at rest and during exercise. This method was devised by Milic-Emili's group in 1996/97 and is a tremendous leap forward in lung function technology and I believe will play a major role in occupational lung disease and medico-legal cases involving spirometry. Will the "big kit" manufacturers incorporate this feature on their future equipment? I would hope so! Prices are about £4000 for the software and hardware together. (*Medisoft, Dinant, Belgium; Fax: ++ 32 82 22 33 34*)

Sleep study and associated equipment

The **SensorMedics** sleep system has been further developed with upgrades of their SomnoStar PT system, Omega24 digital amplification system and AlphaNet sleep study diagnostic and storage network. Prices start around the £35K mark, and are compatible with earlier versions of their own software and archiving databases. Their new product manager for sleep systems is Richard Reading.

The **Jaeger** Sleep system was on show at Geneva and incorporates an option for video images too. Personally, I approve given my interest in video polysomnography in the mid 1980's - since there is nothing which confirms the interpretation of the "wiggles" you see before you than looking at the video. Prices are around £40K plus more for the video option.

Ferraris are now selling the **Judex Nightingale** for Windows NT Sleep system from Denmark. The system offers a very simple to use windows-based software which

has a very logical front-page and has all the usual features of auto-analysis of apnoeas, desaturations and sleep staging, with an option of manual editing. They offer a range of 8 to 32 input channel amplifiers, and a variety of configurations of ambulatory, bedside and remote recording options. Prices start at around £25K with a further £5K for each additional remote option. Contact Kevin Budd at Morgan Medical for more details. As the advertising slogan could say - practice safe recordings in bed - always use a Judex!

Finally, I have received information on the **Nicolet Voyageur Pro** Workstation which uses digital EEG and is predominantly a full EEG testing system but can be used for polysomnography also. The basic system starts at £42K with an additional £10K for the automated synchronised Video Acquisition package. They also offer the option of a rental agreement of either £3526 per quarter over 3 years or £2311 per quarter over 5 years. This has the potential to actually be cheaper to the hospital than outright purchase in the long-term. (*Nicolet Biomedical, Warwick, UK Fax: 01926 490888*).

Many of the sleep study software format and functions produced by the different manufacturers are now fairly similar. The choice of which to buy is very much down to individual taste, good company back-up and the right price. Gone are the days of multi-channel chart recorders, racks of amplifiers and a spaghetti of electrodes/wires- these days a small "black box" and a notebook PC with appropriate "docking terminal" is all we need. We've never had it so good, but if only the prices came down a bit! Unfortunately, the market is driven by the private insurance sector in the US and Europe.

I have it on good advice from Tim Newby at Sunrise/DeVilbiss that an improved version of the RM50 is to be launched - likely to be named the RM60. (Any guesses what the one after that will be called?)

Miscellaneous

The **ERS** has commissioned a re-write of the Buyers Guide for March 1999, to contain a directory entry for - Spirometers, Exercise systems, Nebulisers & Ventilators. The aim is to produce a guide of what equipment is available, and to compare, features, standards, availability in each country and prices.

Deva Medical are now agents for the "most comfortable mask in the world" - the Blue Horizon Gel Mask (aka "The Phantom") by the US company SleepNet. This one-size nasal mask is very soft and may offer the ideal solution to that particularly difficult patient you may have on the books. They are priced at £79.50 (excl VAT) but this includes the headset as well. Whilst I don't envisage having a drawer full of these, I would reckon one or two on standby would be good value for that tricky NIPPV set-up on the Assessment Unit!

I have received a circular from **Friday Medical** regarding rumours about operation of the company. Unfortunately Friday Medical products do not currently have CE marking but can however, be sold under an exemption clause for products currently being dispatched. It is not for this column to comment further on rumours about Friday Medical (see above!).

I see that Instrumentarium Corp. Helsinki, Finland have acquired Ohmeda Medical Systems (most famous for their pulse oximeters) and combined Ohmeda with their Datex-Engstrom division to form **Datex-Ohmeda**. Datex make a

Continued on Page 11

lot of critical care monitors/ anaesthesia equipment and offer a superb range of gas analysers (often used by lung function companies!) and their outstanding Deltatrac Metabolic Monitor. This sounds like a good partnership - we hope the best of both companies develops and grows.

Finally, we have had a good response from manufacturers to exhibit at the Winter Meeting in Doncaster- places are going fast - so book early to avoid disappointment, a drop in sales, a slump in profits and the appointment of a new MD and sales team!!

3. COMPLAINTS DATABASE AND WATCHDOG.

Feedback on **EME/SensorMedics** VMAX 229 problems. I have only received written comments from two SensorMedics users. Both centres have concerns about the nitrogen washout method, "expensive gas cylinders", "poor engineer back-up and knowledge" and "numerous module swaps". One centre found it easy to clean, fast to use, and excellent exercise and hyperventilation testing facilities.

The other centre found the lung volumes to be overestimated, the small calibration cylinders leak very easily - and cost a lot to replace (£90?). The service contract does not make it clear that you need a 6 monthly analyser Perma-pure replacement. However, they did say that the software was excellent and that when it worked the system was very good.

One other criticism was the fact that the company did not know the equation used to calculate FRC - which is a problem I also heard at an ARTP assessment recently! The company issued a support update in October and are circulating customers with a questionnaire about their service and products. We would be pleased to hear of the outcome of that survey.

Chris Baxter at EME has written to me regarding the issues raised here. The small cylinders are designed to keep the systems portable - but this is a feature rarely required in the UK. The larger ED cylinders contain 560 litres and work out cheaper. The smaller the cylinder, the more it is changed the more wear and tear on the "O" rings. Chris informs me that EME engineers are undergoing substantial further training to improve service since their recent takeover, there is also improved quality control of newly delivered systems as well as a review of customer service contracts. Finally, the equations for calculating lung volumes by nitrogen washout technique were enclosed but I won't reproduce them here. The company is prepared to listen to suggestions to improve their service either sent through this column, or directly to EME (Fax: (01273) 645101 or Email: cbaxter@eme-med.co.uk). We'll update you on progress.

We have had personal experience of problems measuring lung volumes whilst evaluating the **Jaeger MasterscreenPFT**. We have found an over-estimation in measuring lung volumes by helium dilution of between 550-770ml difference between the Jaeger and a Morgan Model C machine. I have had another report of a similar sized difference between the Masterscreen and its forerunner the MasterLab. Jaeger are currently working on solving these problems. There are also problems with a new system put in to a hospital close to Nottingham. Early indications are that two new Masterscreen PFT

systems produce very different values in the same subject. Updates will follow.

When writing to the Complaints Database and WatchDog, please state (i) exact dates, (ii) names of people you dealt with and (iii) state clearly your grievance. Also, give a summary account of the history of your complaint (a maximum of one page of A4). There is no need to send photocopies of correspondence at this stage.

Dr Brendan Cooper, (ARTP Manufacturer's Liaison Officer) Lung Function Department, Nottingham City Hospital, Nottingham NG5 1PB. DDI/FAX (24 hours): 0115 840 2615

APPENDIX

CODE OF CONDUCT FOR MANUFACTURERS DEALING WITH ARTP MEMBERS

1. There should be no direct criticism of named or un-named personnel from rival companies or other hospitals or departments.
2. "Word of mouth" rumours about competitors alleged problems should stop unless substantiated by written evidence on official headed paper by a named individual.
3. Criticism of other companies methods and techniques should be limited to published independent scientific trials in reputable journals. You must not give grounds for a customer to doubt a rival company or its representatives knowledge or performance unless this is substantiated in writing.
4. Standards of pre-sales and after sales service must be to the highest acceptable professional standards. Response to complaints should be prompt and constructive.
5. Companies and their representatives should be truthful, competent and accurate when describing their merchandise and service. If companies have criticisms of techniques and methods used by competitors they should be addressed through the Inspire column and competitors should have a right to reply (preferably in the same issue).
6. Representatives must not use their position to establish improper personal relationships with customers; they must not improperly disclose or misuse confidential information about a customer and they must ensure that they do not express personal views about lifestyle, culture, beliefs, race, colour, sex, sexuality, age, social status or perceived economic worth.
7. Representatives of companies who break this code of conduct will be reported to their managing director and other appropriate body regarding quality of service (e.g. ISO9000). Companies must not operate price-fixing cartels or other unfair practices that exploit customers.
8. It is totally unacceptable for any company representative to offer a payment of gift (other than nominal gifts) to an ARTP member to "buy favour". Such offers should be reported to ARTP Executive so that action may be taken against the individual. Fees must not be paid to meet customers.
9. Manufacturers must contact the employing body of any individual for whom they have reasonable grounds to suspect that individual is acting unlawfully or dishonestly. If there is good enough evidence to do so, the ARTP Executive should also be informed in writing.
10. When departments and manufacturers set up contracts to perform research, there should be no "gagging" clauses if the research uncovers findings which could be detrimental to patients and other users of that equipment.

The aim is to promote the highest standards of professional practice just as we would expect our own members to follow our own Code of Conduct. Better professional standards can only improve the standing of all the manufacturers, trust in their products and services and a more just market place based on fair competition and good quality rather than dubious dealing and cosy cartels. We hope to move soon to a policy of approved manufacturers who would agree to abide by this code of conduct. We throw down the gauntlet!

CALENDAR OF FORTHCOMING EVENTS

January 15 - March 1st 1999

Asthma therapy: From basic to clinical research
Internet/intranet telesymposium
More information from S Skinner, Telesymposia
Proceedings, Prous Science, PO Box 540, 08080
Barcelona, Spain. Tel: 34 93 459 2220. Fax: 34 93 458
1535;
e-mail: ts@prous.es;http://www.prous.com/ts

21-23rd January 1999

ARTP WINTER MEETING
Doncaster Racecourse Conference and Exhibition
Centre

February 16 -17 1999

International conference on health effects of vehicle
emissions
London
For more information contact R Smith at Energy
Logistics Ltd
Tel 01628 671717

19th - 23rd April 1999

Short Course in Advanced Respiratory Physiology
(incorporating the HTEC Specialist Option)
Coventry University
Topics include: Exercise testing and interpretation;
respiratory control mechanisms, sleep apnoea
assessment and management, inhalation therapy.
FEE:- **£150** for week (or **£30 /day**)
10% reduction for ARTP members
Quote ARTP membership number on application form.
Contact Anna Kovalchuk (Biology Office) for
application form on 01203 631313

14 - 15th April 1999

Practical Pulmonary Pathology
Brompton Hospital London
FAX: B Corrin on 0171 351 8293

24th -28th April 1999

ATS Annual Congress
San Diego, California USA
Information from ERS HQ
Fax Switzerland 41 21 617 28 65

8 - 10th June 1999

Asthma: the agenda for the next millenium
London
The National Asthma Campaign
Tel: 0171 226 2260

September 1999 (date to be confirmed)

Advanced Respiratory Physiology (week 2)

Coventry University
Topics:- Bronchial challenge and skin testing, Gas
transfer and measurement of lung volumes, respiratory
muscle measurement and flow-volume loops, invasive
and non-invasive blood gas measurement. Respiratory
and cell physiology.

9th-13th October 1999

European Respiratory Society
Madrid, Spain
NB Abstract deadline March 23rd 1999
(abstract forms may be obtained from the ERS Paris
Office)
Tel: (33) 1 45 44 85 84
Fax: (33) 1 45 44 34 11

DO THEY MEAN US?

Laura Watson – Senior Chief Technician, Lung Function Laboratory, QMC, Nottingham

The table below was taken from an article in The Sunday Times (13th September 1998) detailing governmental changes to the British class structure, as from October 1998 Britain will be officially segregated into 17 classes. These classes will be determined by a range of factors including how highly the employee is valued by their employer, how many perks they receive and how stable their job is. Emblems of class have changed over the past few years; before they were largely to do with where you went to school and which family you were born into, today they are more to do with money, property and the job you do.

All statistics collected by the government will adopt the new 17 class system, which should be in place in time for the next census in 2001

The original article detailed winners and losers in this new system; an example of a winner being nurses, who have now risen to the rank of associate professional class 4. Among the losers they named shop assistants (previously regarded as non-manual workers) who have now been placed in the working class. Interestingly, 5 places below the working class shop assistant is rated the lowly medical technician.

This is yet further evidence that our job title needs to be urgently reviewed. Despite improved technician training and education we will continue to be viewed (by the government, if not the general public and more worryingly other professions) as a class below traffic wardens (no offence intended!) instead of along side (if not above!) nurses as the highly responsible health care professionals we are.

WHO'S UP	WHO'S DOWN
• Teachers	• Shop assistants
• Policemen	• Nursery nurses
• Librarians	• Plumbers
• Underwriters	• Traffic wardens
• Managers of more than 25 people	• Dental nurses
• Nurses	• Medical technicians
• Sales managers	• Lorry drivers
• Computer engineers	• Painters, decorators, carpenters
• Prison officers	

Quick Road Test: Bi-Level Positive Airway Pressure Machines:

**Breas 102 (Deva Medical), Respironics BiPAP S/T-D 30 (Medic Aid),
Healthdyne Quantum PSV (S.L.E. Ltd), Sullivan VPAP S/T (ResMed UK).**

This new feature aims to do for *Inspire* what Jeremy Clarkson does for the Reliant Robin (the real one!!!) The plan is to just briefly give a personal review of some similar sets of equipment I have tried in recent months. Whilst this will not be as good a thorough scientific comparison, it will briefly highlight the good and bad points of each piece of equipment. It will hopefully help you to make your own decisions about what you buy.

Best [1] Worst > [4]

	Breas 102	Quantum PSV	Respironics BiPAP S/T-D30	Sullivan VPAP S/T
List price (excl VAT)	1 (£2000)	3 (£3000)	4 (£6000)	2 (£2500)
Size (W x L x D)(cm)	1 (29x14x22)	3 (21x32x33)	4 (20x23x46)	2 (14x24x356)
Weight (kg)	2 (3.5)	3 (7.6)	4 (8.2)	1 (3.5)
Sound level	4	3	2	1
Ease of set up	3	2	1	4
Controls	2	3	1	4
Insp trigger	Yes	Yes	Yes	Yes
Exp trigger	Yes	Yes	No	Yes
Breath rate (bpm)	6-40	4-40	4-30	5-30
Ramp feature	Yes	Yes	Yes	Yes
Pres range: IPAP	4-30	2-37	4-30	4-25
Pres range: EPAP	4-IPAP	2-25	4-30	2-IPAP
Lock feature	Yes	Yes	Nearly	Yes
Modes S(pontaneous)	Yes	Yes	Yes	Yes
T(imed)	Yes	Yes	Yes	Yes
S/T	Yes	Yes	Yes	Yes
Alarms	Yes (Power)	Yes (Several)	Yes (Option)	No
Output	RS232	Analogue	???	???
Reliability	Unknown	OK	Good	OK
Running costs	OK	OK	Filters	OK
Power				
(115-120 / 220-240 V)	Yes	Yes	Yes	Yes
Total	13	17	16	14

OVERALL VERDICTS:

Breas 102

Whilst it is cheapest, and it is small and versatile, it is noisy and a bit fiddly to set up for the first few times. However, if you are used to other Breas machines, it would make a logical choice for ward staff. Software is available to determine patient usage whenb connected via RS232.

Quantum PSV

This is overall the the worst machine here, but it is very easy and logical to set up. I like it as an acute ward use Bi-level PAP machine, but it is slightly old technology now. Probably over-priced.

Respironics BiPAP S/T

Although this machine was the mould-breaker, because of its old technology and large size it is over-priced for the home ventilator market. Again, it may be worth having one on the acute ward - but you could have at least two of the other machines for the same price! This model is being replaced by a new model which costs £12,000.

Sullivan VPAP S/T

This machine runs a close second to the Breas. Its LCD display is, on reflection, a bit fiddly with almost too many options - but once familiar to the user offers great versatility. It is so quiet, you need a stethoscope to check that it is on!!

FINAL COMMENT:

Personal preference will decide which of these machines you like. Who will be using them, where will they be used, how much do they cost to run, how much capital do you have in the first place - these issues will all determine your choice in the end. I would buy either the Breas or the Sullivan for patient issue, and use any of them on the ward.

AUDIT OF DISINFECTION OF RESPIRATORY FUNCTION EQUIPMENT IN TRENT REGION

Dena Muirhead, Senior Chief Technician

CARDIOTHORACIC MEASUREMENT DEPARTMENT, DERBYSHIRE ROYAL INFIRMARY

INTRODUCTION

The disinfection/decontamination of Respiratory Function equipment poses many problems. The main concerns of any Respiratory Laboratory are that the risk of cross infection between patients is reduced to a minimal level with the processes used. Currently National Guidelines are not available so departments have to take advice from the manufacturers of the equipment and liaise with the Local Infection Control Team.

The practicalities of this means that equipment is cleaned using the best of the resources available in that hospital.

The disinfection processes which can be used include:- a hot wash disinfection process; cold sterilising solutions; low temperature steam; Ethylene Oxide and Hypochlorite solutions.

There are potential problems with all of these methods:-

Low temperature steam and Ethylene Oxide are not readily available in all hospitals. The increased use of cold sterilising solutions is not advocated by local Health and Safety Advisers due to the hazards associated with these substances to staff from potential exposure. An effective ventilation system must always be used. Staff should receive health surveillance effective training and regular monitoring of the process should occur.

Many of the hot wash systems in the local TSSU/CSSD units use temperatures, which exceed the heat stability of the materials used in the equipment. A melted unusable tube has been returned on more than one

occasion from the local TSSU at our hospital.

Milton can be used but is not as effective as other methods and probably better for small items. Corrugated tubing presents a further problem in that we need to ensure that the disinfectant process used reaches all internal parts. Air pockets can be a problem if the tube is to be immersed.

Finally, drying of equipment to prevent micro-organisms re-growing is essential. Mouthpieces and valves are easily dried but tubing can be more difficult.

Frequency of disinfection was also an issue. Daily disinfection is not ideal due to micro-organisms accumulating over the day's use but changing tubing between patients is not always practical.

These problems and issues were of great concern to the Respiratory Laboratory and after discussion with the Infection Control Team and Microbiologist, we felt an audit of the methods used in Trent Region would be beneficial, with a view to setting up a working group and drawing up guidelines for Trent Region.

METHOD

A questionnaire was circulated to 10 departments in Trent Region. Initial questions ascertained the existence of local policies and interest in setting up a working group and drawing up a policy.

Departments were asked how individual components of the equipment were treated in terms of cleaning, disinfecting and drying. They also had to indicate frequency of

cleaning. Spirometer, gas transfer equipment, turbine and pneumotachograph systems were included in the audit.

Departments were given the opportunity to give additional information and enclose policies.

Departments were also asked to indicate if they used filters.

All 10 departments returned the questionnaire.

RESULTS

All departments wanted to set up a working group so that guidelines for Trent Region could be drawn up.

Local Policy

60% of departments had a local policy

40% of departments did not have a local policy

Cleaning Prior to Disinfection, i.e.

Disinfection wipes	10%
General detergent Hospec	50%
Hypochlorite	10%
Haz tabs	10%
Travasept	10%
Hibiscrub	10%

Filter Usage

7 departments did not use filters, 3 of which occasionally used them in infectious cases and immuno-compromised patients.

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METHODS OF DISINFECTING EQUIPMENT

Equipment	CSSD/ Hot Wash	Milton/ Saniclor	Ethylene Oxide	LTS+	Milton Hot Wash 65°	Autoclave	Alcohol Soln	Not Specified	Other*
M Pieces	50%	20%		10%	10%			10%	
Tubing		41%	41%	9%	9%				
Valves		30%	20%		10%	10%	20%		10%
Open Devices		50%					20%	30%	
Spirometer Internally		30%					40%	30%	
Gas Transfer Internally	10%	10%	10%				20%	50%	
Noseclips					100%		30%	20%	40%

* Other includes tissue, hibiscrub, soapy water + Low Temperature Steam

FREQUENCY OF CLEANING

Equipment	Sessional	Daily	Weekly	Other	Between Patients	N/A
M Pieces					100%	
Tubing	20%	20%	30%	30%		
Valves	10%	30%	20%	20%	10%	
Open Devices	10%	50%	20%			20%
Spirometer Internally		10%	50%	40%		
Gas Transfer Internally		20%	40%	50%		

CONCLUSION

Several methods of cleaning/ disinfection were being used throughout the region, with some departments following similar methods.

Types of disinfection used appears to be dependent on the available resources within that hospital, e.g. 2 hospitals have Ethylene Oxide and low temperature steam available and use this resource. Both methods are recommended for the tubing available from a well known supplier of respiratory equipment.

There is some debate over the use of filters, with the majority of departments not using them. Reasons for this were based on cost and the conflicting evidence on how effective filters are. Some departments used filters for immuno-compromised and infectious cases.

Those departments sending equipment to CSSD were not always specific regarding the process used, and this needed further investigation.

All departments recognised hazards associated with cold sterilising solutions and were avoiding their use.

Many departments used Milton based solutions for cleaning items as previously discussed, this is not ideal for larger items.

Departments used various methods of cleaning prior to disinfecting. Proper cleaning prior to disinfecting is paramount to remove any visible soiling.

There was wide variation in the frequency of changing and cleaning equipment.

SUMMARY

In summary the audit showed that differences did exist in both cleaning

and disinfecting methods throughout the region with only two departments having facilities for LTS and Ethylene Oxide, which are both effective and recommended by manufacturers for disinfecting equipment. Frequency of changing and cleaning of equipment varied greatly.

While manufacturers can give guidance on disinfection for their particular equipment, this does not take into account the accessibility of this process to the laboratory. Infection Control can then advise on best practice but this varies between hospitals.

There is no doubt that Respiratory Laboratories need not only local but National Guidelines from our Professional Organisations to follow so that an informed decision can be made on the process to be used and therefore, minimise the risk to patients.

Infection Control Recommendations

B G COOPER

Nottingham City Hospital, NG5 1PB

Aim:

To provide comprehensive recommendations and principles of good practice in infection control for all users of lung function and related equipment.

Scope of the Guidelines

These guidelines are aimed at responding to the immediate requirements of ARTP/BTS members in advance of the ERS Working Group on Infection Control. They will be revised in the light of the report of that working group, but will provide essential information to practitioners of lung function equipment in the interim.

Lung function equipment:

(spirometry, lung volumes, gas transfer, exercise systems, body boxes)

Associated equipment:

(blood gas machines, sputum collection, oximeters, sleep study equipment)

Home Ventilators:

(CPAP, BiLevel, NIPPV, masks, headgear, etc.)

Inhaler devices: (Nebulisers, spacers, MDIs, etc.)

Background

What are the risks?

Risk assessment involves frequency and consequences of a detrimental event happening. The main risks considered here are;

1. Cross infection of pathogenic organisms between patients (i.e. increase morbidity)
2. Cross infection of pathogenic organisms to an immuno-compromised patient (i.e. increase mortality)

The frequency of the chance of cross infection must be high, because there are 1000s of LFTs performed every day nationally. The consequences vary from minor inconvenience (i.e. catching a cold) to moderate (i.e. extending hospital stay) to severe (i.e. contributing to patient's death). This will obviously depend on (a) the virulence of the bug and (b) on the health status of the patient who is being infected.

Pathogens can be broadly categorised by their risk level as follows (Table 1):

TABLE 1

Consequence	Risk factors and Infection Type		
	High	Moderate	Low
	MRSA	Pneumonias	Common cold
	TB	Viruses	Mouth infections
	HIV	Herpes simplex	
	Pseudomonas cepacia		
	Pseudomonas originosa		
	Hepatitis B		

Source of the infection

Airborne from lung function equipment, coughing, sneezing, dust, etc.

Body fluids from sputum, phlegm, blood, etc.

Particle sizes (comparative sizes)

The sizes of airborne particles of infection are shown in Table 2 and are related to other airborne substances that may be breathed in. This can be related to the grade of filters available to stop these particles being transmitted to equipment.

Evidence for cross infection from lung function equipment

To date, there is only one documented case (Hazaleus et al, 1981) of cross infection from lung function equipment to patients. Generally, there is no published clear evidence (Kendrick & Viant, 1986; Gold et al, 1982; Elder & Sauer, 1977; Renfrow et al, 1985) for cross infection from lung function equipment, a point also reported by Hazaleus et al. Conceptually, you would expect some risk from sequential patients breathing into the same equipment and there is evidence for micro-organisms in lung function equipment (Kendrick & Viant, 1986; Renfrow et al, 1985; Depledge et al, 1981; Houston et al, 1981; Isles et al, 1984). Clearly anaesthetics and ventilators do present a greater risk of cross infection and there are a few proven case reports.

The challenge is to apply common sense to the potential risk so that it becomes either a zero or an insignificant risk. Hospitals are relatively "unhygienic places" where people with infection are concentrated.

TABLE 2

Particle size band (Microns)	50	10	1	0.1	0.01
ASBESTOS FIBRES					
CEMENT DUST					
PLANT SPORES & POLLENS					
BACTERIA					
ATMOSPHERIC STAINING					
EXHAUST FUMES					
TOBACCO SMOKE					
WELDING FUMES					
VIRUSES					

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Useful definitions: The world of infection control like most specialist subjects involves considerable jargon, abbreviations and buzz words. The following are offered to aid understanding for the beginner.

- Sterilisation:** complete destruction of all micro-organisms and their spores.
- Disinfection:** destruction of potentially pathogenic micro-organisms, but not their spores.
- Electrostatic filter membrane:** a charged material that "traps" particles and organisms.
- Pathogenic:** disease producing
- Nosocomial infection:** an infection obtained in hospital.
- Pleated filter:** folded material (usually offering high resistance)
- Filter efficiency:** the ability of the filter to trap bugs as tested independently using a test rig. (dependent directly upon flow).

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BS 3928-Sodium flame tested

- ISO standards – International Standard - worldwide levels of acceptable quality for manufacturers
- BS standards – British Standards - national levels of acceptable quality for manufacturers
- MDA – Medical Devices Agency - quango responsible for maintaining standards in medical equipment.
- COSHH – Control of substances hazardous to health
- CSSD – Central Surgical Sterilisation Department
- MRSA – Methocillin Resistant Staphylococcus aureus - a particularly infectious organism that is multi-resistant to many antibiotics.

Methods of controlling spread of infection: cleaning programmes vs filters

There have been no published prospective trials of these two different methods of infection control in the lung function environment. Clearly, it is difficult to determine which of these two methods solves *the problem* when there is little evidence for *the problem* being there in the first place! However, many departments through the guidance of Infection Control departments undertake equipment cleaning programs and/or use of filters. This

section will describe some of the recommended cleaning procedures, together with their advantages and disadvantages. Air filters will be given the same evaluation.

CLEANING PROCEDURES

Types of cleaning agents - how they work, when to use

Cleaning of equipment involves the destruction of pathogens either by physical (e.g. heat, irradiation) or chemical (e.g. glutaraldehyde, ethylene oxide, hypochlorite solution, etc.) means.

All the methods have advantages and disadvantages based on cost effectiveness, suitability for the material or object being decontaminated, ease of use and availability. Firstly, consider the reagents available for cleaning (Table 3).

The frequency of cleaning

This will depend upon (i) the type of equipment being used, (ii) the frequency of testing, (iii) the ease of disassembly/assembly of the apparatus (iv) the manufacturer's recommendations, (v) the time/staff available for cleaning the equipment.

"Best practice" would include daily, weekly and monthly documented cleaning procedures to various pieces of equipment in the laboratory.

TABLE 3

Cleaning agents		
	Mode of action	
	Disinfect/ Sterilise	Effective against
Low temp steam	D	Most bacteria and viruses
Low temp steam & formaldehyde	S	Most bacteria and viruses
High temp steam	S	Most bacteria and viruses
Hot water (70C) & detergent	D	Most bacteria and viruses
Milton (%)	D	Most bacteria and viruses
0.5% Chlorhexidine	D	Most bacteria and viruses
Glutaraldehyde	D/S	All bacteria and viruses
Ethylene oxide	S	All bacteria and viruses
Alcohol (70%)	D	Most bacteria and viruses

TABLE 4 Cleaning equipment: specific advice

N.B. It is essential to read the manufacturers instructions before undertaking any cleaning procedure particularly with regard to electrical safety and avoidance of damage to the equipmant with cleaning agents.

Equipment	Infection	Agent	Procedure	Frequency
<u>Sleep study equipment</u>				
Sleep apnoea holter	MRSA, virus, Staph.	Alcohol	Wipe outside	After each pt.
Sleep apnoea m'phone	MRSA, virus, Staph.	Alcohol	Wipe outside	After each pt.
Sleep apnoea sensor	MRSA, virus, Staph.	Ethyl Ox	D'cont'm'ate	After each pt.
Pulse oximeter probe	MRSA, virus, Staph.	Alcohol	Wipe outside	After each pt.
Airflow sensor	MRSA, virus, Staph.	Deterg't/1:80 Milton	Wipe outside	After each pt.
<u>Miscellaneous</u>				
BP cuff	MRSA	Hypchlorite	Soak	After cont'm'n
Nebuliser mask	TB, bact, virus	1:80 Milton	30 mins soak	After each pt.
<u>Lung function equipment</u>				
Vitalograph	MRSA, TB, bact	Glut or LTS	????	After cont'm'n
Corrugated tubing	HIV, bact, virus	LTS		Weekly
Cond'n trap	bact, virus, etc	Chlor'x'n	Soak	Weekly
Peak flow meter	virus, fungus, etc	Brush	Clean	After each pt
Noseclips (sponge)	MRSA, virus, Staph.	Ethyl Ox	Soak/discard	
Noseclips (foam)	MRSA, virus, Staph.	Alcohol	Wipe outside	After each pt.
Noseclips (rubber)	MRSA, virus, Staph.	Alcohol	Wipe outside	After each pt.

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Other infection control procedures:

Gloves - these cut down the risk of cross infection from bodily fluids between patients.

Hand-washing - this is the single most successful way to stop the spread of infection. Remember, shaking hands and then rubbing your eyes is now thought to be the most likely way that the common cold is spread from person to person!

Regular cleaning of department work surfaces, walls, floors, etc. will stop the build up of colonies of organisms.

Disposable mouthpieces - these are essential nowadays for spirometry/peakflow measurement.

One-way mouthpieces - enable expiratory manouevres with little risk of patients inhaling infection from previous patients.

FILTERS

Issues to consider when purchasing filters.

When choosing to use a filter suitable for lung function testing the following criteria need to be considered. The information listed below should be clearly provided by the filter manufacturer with independently tested data on the performance of the filter from one of the following centres:

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University College of Wales,
Medical Devices Directorate.

Type of filter

Electrostatic filter membrane: a charged material that "traps" particles and organisms. How does this perform when wet.

Pleated filter: folded material (usually offering high resistance)

Testing the filter

Filter efficiency: the ability of the filter to trap bugs as tested independently using a test rig.

- (i) This is dependent directly upon the flow at which the filter was tested.
- (ii) Was the filter dry or wet, what is the efficiency when wet?
- (iii) Was the filter new or old
- (iv) What is the variation in batch?

You will find that manufacturers of filters will quote the *Initial arrestance* - the effectiveness of their filter against larger particulate matter when it is new compared to the average arrestance which is measured over the filters life.

What was the particle/pathogen size used in the test?

Reference to Table 2 should help you decide which filter will be most appropriate (i.e. was this smaller or larger than the bugs your equipment may be exposed to)?.

Has the filter come up to the following standards?:

BS 3928-Sodium flame tested

ISO standards International Standard - worldwide levels of acceptable quality for manufacturers

BS standards

British Standards - national levels of acceptable quality for manufacturers
Medical Devices Agency - quango responsible for maintaining standards in medical equipment.

MDA

Performance of the filter

What is the dead space of the filter?

This is important particularly when measuring expired gases (e.g. gas transfer test). You will need to know this to make corrections to lung volume and gas transfer calculations. Many equipment manufacturers offer software which allows you to adjust dead space for different filters.

What is the resistance of the filter to flow?

Some filters offer a resistance to flow which produces lower PEF values, and in the worst cases poor patient effort and therefore reduced FEV1 and / or FVC, (Denison, 1989).

What is the cost of the filter per patient?

The costing of the filters needs to be thought through carefully. Target prices are currently between £1.50 - £2.00 each which means in a busy department (e.g. 8000 spirometries per year), new budget of between £12,000 and £16,000 per year needs to be found!. This is often difficult to obtain from hard-pressed sources of funding but needs to be considered in the hospital's overall Risk Assessment process.

When analysing the costs of all forms of infection control, the "full picture" needs to be considered, so that the following are included in the costings:

Technical time: dismantling equipment, cleaning, re-assembly and checking.

Costs of cleaning agents, protective equipment, disposal of waste material.

Administrative costs: ordering materials, filters, etc.

Costs of power, depreciation of equipment, etc.

How long is the system out of action during cleaning (loss of "revenue" or effectiveness)

Is it disposable or reusable or semi-disposable?

Semi-disposable filters, can reduce the cost considerably, but increase operator time in cleaning and looking after the filters. Errors in their re-assembly could compromise their protective ability.

Which filter should I buy?

There are few published, clear, independent trials of commercially available filters for use in the Lung Function laboratory. Reports in abstract form show poor protection from the Collins DC-1 and Pall PF305 (Pryce Roberts & Leeming) although better performance from the Spiroguard (Air Safety, UK) and Vitalograph bacterial filters (Milkins et al, ERS 1998). The ERS has set up a working party to report in the next two years on the performance, effectiveness and value for money of filters and infection control. In the meantime, best practice will be determined by informed reviews and local policy.

Summary

These guidelines offer information on how to select a method of infection control for the lung function department. The choice of method will depend largely upon local policy, finance and the number of tests and the type of patient being tested.

Clearly some patients need protecting from infection (transplant patients, immuno-compromised patients, etc.), and others need to be stopped from spreading infection (those with MRSA, TB, HIV etc.). Common sense and understanding of the scale of the problem need be considered in a manner appropriate to the specific circumstances.

Until definitive studies have been performed, it is not yet possible to recommend any single method of infection control in the lung function laboratory and general practice. Many centres are limited to the manufacturer's recommendations by risk management policy, but hopefully this article will inform users and help individuals balance up the arguments for what they should be doing in their practice.

Specific Cleaning Processes

Some guidelines on how to clear up specific types of common spillage are summarised below:

Blood spillage

1. Put on protective gloves, a protective apron and protective glasses and mask in cases of large spillages (1 ml). For a minor spillage (i.e. a drop), gloves should be sufficient.
2. Isolate the spillage area.
3. Use absorbent disposal towelling to absorb as much of the blood as possible. Beware of broken glass if a sample bottle has broken (don heavy duty rubber gloves in this case). Use thick layers of towelling to scoop up the blood and place immediately and directly in a clinical waste bin.
ANY GLASS/SHARPS MUST BE PLACED IMMEDIATELY IN A SHARPS BIN!
4. Next wash the contaminated surface with hot water and detergent to clear up any dried blood- again discarding all towels directly into a clinical waste bin.
5. When the area is cleared, wash down with 10% Milton solution, providing there are no metal surfaces. (Otherwise chlorhexidine surface cleaner is acceptable).
6. Repeat step 5 over a wider area than the spillage was contained in.
7. Ensure all waste is safely disposed of.
8. Remove all protective clothing, etc. and wash your hands thoroughly
9. Report the incident in your accident book and follow local policy.

Infected sputum

1. Treat in a similar manner as for blood samples. Wearing of a face mask may be preferable, because of possible generation of aerosolised microbes being inhaled during cleaning.
2. Follow steps 1-9 above.

TB patient exposure

1. If lung function equipment (e.g. mouthpieces, tubing, spirometers, etc.) has been exposed to a known TB patient, the equipment should be removed from circulation immediately.

2. Put on protective gloves and wear a protective face mask.
3. Place exposed parts of the machine in "high risk" bags for CSSD cleaning according to local policy.
4. Usually LTS or glutaraldehyde or ethylene oxide will be sufficient to kill the bacteria.
5. Swabs should be taken after cleaning and checked for TB. Only use the equipment again after the "all clear" is confirmed in writing.
6. Contact the hospital TB nurses if you suspect other patients may have been exposed to TB from the equipment.

Declaration: Whilst every effort has been made to establish "best practice" from the literature, the authors and the ARTP Executive Committee accept no responsibility for the advice given in these recommendations. Final responsibility for adopting the recommendations remains with the reader and their local infection control policy.

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RECENT ARTICLES

The following summarise recently published articles appearing in medical journals which may be of interest to ARTP members

LUNG FUNCTION and DEVICES

Analysis of expiratory tidal flow patterns as a diagnostic tool in airflow obstruction. Morris MJ, Madgwick RG, Collyer I, Denby F, Lane DJ. *Eur Respir J* 1998; 12: 113-117.

Tidal expired airflow patterns in adults with airway obstruction. Williams EM, Madgwick RG, Morris MJ. *Eur Respir J* 1998; 12: 118-1123.

These companion papers consolidate earlier work from the Oxford group, which in 1981 documented the distinctive patterns of tidal breathing loops (airflow vs time) from patients with airflow obstruction. In the first paper (Morris et al) the tidal breathing loops at rest were examined from 118 adult patients. Measurements from the later part of the loop yielded the time constant of the respiratory system and the extrapolated volume (the volume of dynamic overinflation). These indices correlated well with the established measurements of airflow obstruction i.e. FEV₁ % predicted, Raw and FRC % predicted. The second paper (Williams et al) describes a further analysis of tidal breathing in which preset criteria were used to establish a single index of airway obstruction and thus objectively distinguish between normal and obstructed airflow patterns. The tidal loops from 66 adult patients with varying degrees of airflow obstruction were examined. In each subject each consecutive breath was scaled and then averaged to create a single expired pattern. A slope index (S) for the flow beyond the peak tidal flow was established. The index was found to be sensitive to the severity of airflow obstruction and correlated with FEV₁ % predicted. These studies suggest that the simple, non-invasive procedure of tidal breathing at rest may be used to derive an index of airflow obstruction and may be useful as a first line diagnostic tool in the lung function laboratory. The advantages of this type of analysis will be especially useful in infants and children, and in adults who are unable to (or will not - claim cases!) cooperate with the more complicated forced effort manoeuvres. (See also Editorial comment *Eur Respir J* 1998; 12: 1008-1009).

Measuring tidal volume and functional residual capacity change in sleeping infants using a volume displacement plethysmograph. Wilson SJ, O'Brien C, Harris MA, Masters IB. *Eur Respir J* 1998; 12: 1186-1190.

This short technical note reports on the design and performance of a 'head-out' volume displacement body box. Tidal volume, respiratory rate and changes in FRC can be recorded during unsedated sleep with conventional plethysmographic methods. The 'head-out' configuration also allows additional instrumentation to be implemented with ease.

Assessing the effect of deep inhalation on airway calibre: a novel approach to lung function in bronchial asthma and COPD. Pellegrino R, Sterk PJ, Sont JK, Brusasco V. *Eur Respir J* 1998; 12: 1219-1227.

In this review article the authors discuss the physiological and clinical relevance of the inability of the airways to distend after a deep inhalation in both asthma and COPD. The paper examines the maximal and partial flow-volume curves, lung and airway resistance measurements. It also covers the clinical patterns recorded in healthy subjects during induced bronchoconstriction and spontaneous bronchoconstriction in patients. There is a short overview of treatment effects.

Effect of breathing circuit resistance on the measurement of ventilatory function. Johns DP, Ingram CM, Khov S, Rochford PD, Walters EH. *Thorax* 1998; 53: 944-948.

This study determines the resistance of five commonly used spirometers and three peak flow monitoring devices. The back pressure developed in each piece of equipment was measured over a range of known flows. In order to establish how an additional resistance within a breathing circuit affects the common measurements of PEF, FEV₁ and FVC a group of patients and normal subjects performed repeated measurements with four different resistors (1 to 11 cmH₂O) inserted into the breathing circuit. With the exception of one of the monitoring devices all of the equipment passed the ATS guidelines for the upper limit of resistance. The PEF was found to be the measurement most sensitive to added resistance within a piece of equipment. The authors concluded that the added resistances, which were of a similar magnitude to the inherent resistance of the increasingly used barrier filters, were likely to breach the ATS guidelines and have clinically significant effects on measurements of airflow.

EXERCISE

Bronchial obstruction and exhaled nitric oxide response in cold air. Therminarias A, Oddou MF, Favre-Juvin A, Flore P, Delaire M. *Eur Respir J* 1998; 12: 1040-1045.

The aim of this study was to determine whether extensive airway cooling can induce airway obstruction in non-atopic subjects, and also provoke changes in exhaled NO. Eight well-trained normal subjects performed 2 incremental exercise tests to exhaustion, in randomised ambient conditions of 22 deg C and -10 deg C. FEV₁ and flow volume loops were measured before and after exercise, whilst VE, VO₂ and exhaled NO were measured continuously. There were significant decreases in FEV₁, flow volume loop indices and exhaled NO in the low temperature confirming that cold causes a detectable airway obstruction. The fall in exhaled NO was also associated with the airway cooling.

ASTHMA

Methodology of bronchial responsiveness. Susan Chinn. *Thorax* 1998; 53: 984-988.

This review comments on the variations in protocols and the different methods of assessing dose or concentration. It discusses how the results from different methodologies are often non-comparable and finishes with a recommendation of how data should be analysed for epidemiological work.

COPD

Comparison of spontaneous and induced sputum for investigation of airway inflammation in chronic obstructive pulmonary disease. Bhowmik A, Seemungal TAR, Sapsford RJ, Devalia JL, Wedzicha JA. *Thorax* 1998; 53: 953-956.

In this study samples of spontaneous sputum and sputum induced with 3% hypertonic saline for 14 minutes were collected from 27 patients with COPD. The samples were analysed for total and differential cell counts, cell viability and interleukin 8 levels. The induced samples were found to contain a higher proportion of viable cells than the spontaneous samples. The procedure was found to be safe in this series of patients.