Welcome

Welcome to the Jan 2018 edition of NewWave.

If you have any relevant articles or papers that you would like to be included in future editions, please email them to steve.perring@poole.nhs.uk

The AGIP Council particularly recommends that you look at the Department of health’s consultation on healthcare regulation and regulatory structures and the RCCP’s responses to this consultation

You can find this on Page 15 of this edition of NewWave

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<th>Event Details</th>
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<tr>
<td>1st March 2017</td>
<td>AGIP Masterclass in Upper GI Physiology</td>
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<tr>
<td>12th April 2018</td>
<td>Children’ Anorectal Physiology Service</td>
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<td>Practical Workshop for Awake High Resolution Anorectal Manmometry. Wingate</td>
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<td>Institute London</td>
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<td><a href="mailto:CAPS@bartshealth.nhs.uk">CAPS@bartshealth.nhs.uk</a></td>
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<td>18th-20th April</td>
<td>The First Pelvic Floor Summit</td>
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<td>Advancing the Treatment of Incontinence</td>
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<td>International Conference Centre, Telford</td>
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<td><a href="http://www.ukcsconferences.com">www.ukcsconferences.com</a></td>
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<td>15th May 2018</td>
<td>HRM &amp; Impedance/pH Study Day, Manchester</td>
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<td><a href="mailto:info@ardmorehealthcare.com">info@ardmorehealthcare.com</a></td>
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<tr>
<td>2nd-5th June 2018</td>
<td>Digestive Diseases Week</td>
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<td>Washington DC</td>
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<tr>
<td>4th-7th June 2018</td>
<td>BSG Annual Meeting</td>
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<td>09-11 Jul 2018</td>
<td>ACPGBI Annual Meeting</td>
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<td>Association of Coloproctology of Great Britain and Ireland</td>
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<td>28-31 Aug 2018</td>
<td>ICS 2018</td>
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<td>International Continence Society</td>
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<td>20-24th October</td>
<td>26th UEG Week</td>
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<td>United European Gastroenterology</td>
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<td>Vienna</td>
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HRM & Impedance/pH Study Day
Tuesday 15th May 2018
Double Tree Hilton, Manchester

Chaired by Professor Stephen Attwood

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<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
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<tr>
<td>9.30</td>
<td>Registration</td>
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<tr>
<td>9.55</td>
<td>Introduction</td>
<td>Prof Stephen Attwood</td>
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<tr>
<td>10.00</td>
<td>Analysis of 24hr Impedance/pH studies</td>
<td>Dr Arjan Bredenoord</td>
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<tr>
<td>10.30</td>
<td>Impedance/pH case studies</td>
<td>Dr Arjan Bredenoord</td>
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<tr>
<td>11.30</td>
<td>Coffee break</td>
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<tr>
<td>12.00</td>
<td>An introduction to HRM and Chicago 3.0</td>
<td>Dr Arjan Bredenoord</td>
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<td>13.00</td>
<td>Lunch</td>
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Parallel Sessions

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<tr>
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<tr>
<td>14.00</td>
<td>HRM case studies for beginners</td>
<td>Mr Warren Jackson</td>
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<tr>
<td>14.00</td>
<td>Advanced HRM case studies</td>
<td>Dr Arjan Bredenoord</td>
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<tr>
<td>15.30</td>
<td>Meeting close</td>
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Please contact info@ardmorehealthcare.com for details on registering.
There is still time to apply for a place on this course

AGIP Upper GI Physiology Masterclass in Good Practice
Thursday 1st March 2018
Post Graduate Education Centre, Queen Elizabeth Hospital, Birmingham, B15 2GW
Who is Stephen Attwood?
What is he about?
What can he do for GI Physiologists?

The answers to these questions are coming from my perspective and therefore many might disagree! But first the facts (mostly unassailable!)

I am an almost life-long committed oesophageal researcher. During my medical school undergraduate course, I took a year off to do a Physiology research degree and my main project was on the oesophagus – publishing a paper on circadian rhythm of mitotic activity in the epithelium (1978) and also identifying the Langerhans cell in the oesophagus (not published due to lack of interest by my supervisors. Shame really as someone else published this 10 years later!) Lesson number 1 – be open minded and have faith in yourself.

An oesophageal destiny continued to follow me – as I went through my surgical training. I was fortunate to get on a research rotation between Lancaster and Tom DeMeester’s unit in Omaha Nebraska – so I got to learn the art of pH-metry from the great man himself, as well as a little about Oesophageal manometry, from a man called Don Castell – the then president of the American Gastroenterology Association. I greatly enjoyed these experiences – Lesson number 2 – enjoy a good opportunity when you can – they don’t come along every day.

My research project was ostensibly about bile reflux causing oesophageal cancer, with human data and an animal lab model of adenocarcinoma – both very valid in the long run but my contribution only small steps in the general development of the understanding of the relationship of GORD and Adenocarcinoma in Barrett’s oesophagus. Along the way I spent some time writing up apparently smaller projects – although the one that became the first description of Eosinophilic Oesophagitis (1993) has been anything but small, and now occupies much of my time in lecturing, and research on specific drug formulations. (Back to lesson number 1 again)

My main career has been as an Upper GI surgeon, initially broadly so (benign and malignant), but ending up purely a surgeon focussing on benign disease and cancer prevention. The latter has been mainly research on Barrett’s oesophagus in the Aspect trial, UK looking at aspirin and varying doses of PPI finally reporting in 2018 after a 7 – 10 year follow up. I have also run a number of key randomised clinical trials involved in surgical procedures, such as the first RCT of any laparoscopic operation, and a large RCT of antireflux surgery vs ppi (the Lotus trial)

Throughout this time, I have helped to administer and analyse the oesophageal function laboratories in the hospitals I have worked. I still report the output of the GI physiology lab in Northumbria Healthcare (North Tyneside Hospital) as our lab is staffed by specialist nurses who are great at performing the tests but do not do the analysis. Yes – there are arguments for ensuring that the labs are staffed with qualified GI physiologists but this is not always practical. I have previously worked in Manchester (Hope hospital in Salford) where Jo Barlow and Anthony Hobson were formative in my mid term development in GI Physiology.
Academically, I am linked to Durham University as a Professor in Health Services Research, and I have been fortunate to have had a very large output in research publication. As a consequence, my working life is now almost entirely involved in research and teaching, managing collaborative projects across the UK and in the USA and Europe. My link with the Physiology lab continues on one day a week, but the remainder sees me out and about across the globe. I get to meet the most interesting people in the most interesting places – such as Birmingham AGIP conference last year – which resulted in my acquaintance with the AGIP committee and recent appointment as a clinical member of the committee. (Lesson number 3 – don’t judge the book by its cover - AGIP and Birmingham not immediately sounding exotic and captivating but currently of great interest to me!)

I am helping to direct the research into the Electrical neuromodulation of the lower oesophageal sphincter (EndoStim) for the treatment of GORD, and also to introduce a new form of topical steroid (budesonide – JORVEZA), the first drug licenced (just last month) for the treatment of eosinophilic oesphagitis. As Chairman of the Oesophageal Section of the BSG I have a commitment to writing clinically relevant Guidelines - there are important topics such as Therapeutic Dilatation of the Oesophagus – which we will publish in Gut in early 2018, and a new guideline on Oesophageal Physiology testing later in the year. Lots there relevant to practicing GI physiologists.

Steve Perring asked me for some personal interest. Well, I enjoy managing a small holding of woodland and a Victorian Walled Garden in Northumberland. I don’t need a gym membership because doing forestry and hauling logs is cheaper! and I like to cycle in the hills and to run cross country. (Picture with Matt Baker of the One Show on the Rickshaw challenge last year, and picture with wife Ann on a cycle, London to Paris). As a consequence of these activities my lawn had been neglected but is now well catered for by my new friend Sam – the Semi Automatic Mower pictured – supposed to be fully automatic but someone has to rescue him from the flowerbeds once every so often!

The other picture is of Rami Sweiss – also a Doctor on the AGIP committee. The lesson number 4, from this photo is – Learn to collaborate. The days of Isaac Newton discovering gravity by watching an apple fall from a tree are rare events. Working as a member of a collaborative team is what gets results that are relevant and interesting to broad members of our scientific and clinical community. Rami and I work on a number of research projects together, as well as on the Oesophageal Section committee of the BSG. Both of us wish the members of AGIP a Happy 2018 and a productive future in our business of caring for patients with oesophageal diseases and dysfunctions.

Lastly I am available to help any AGIP member with clinical or scientific analysis and I look forward to seeing you all at the AGIP conference in March

Stephen Attwood
With Matt Baker

New friend Sam

Stephen and Rami in Galway
Meet the New Members of the AGIP Committee
Rami Sweis
President of AGIP

Rami is not technically a new member of the Committee, but he has recently taken over the presidency of AGIP and, though he needs no introduction to most of us, I asked him to give us a potted biography of his career thus far

Steve Perring

Rami Sweis acquired his Bachelor’s degree in 1994 from the University of Illinois at Chicago and his medical degree in 1999 from University of Edinburgh. He trained in gastroenterology at Guy’s & St Thomas’ Hospitals, Kings College Hospital and South East Thames and completed his PhD from Kings College London in 2012. He was appointed as Consultant in Upper GI Medicine and Physiology at UCLH in 2014 and is the Upper GI Physiology Lead. He also holds an Honorary Clinical Senior Lecturer position at University College London.

Rami Sweis’ research is primarily focused on trying to advance the methodology and utility of the technology used to investigate reflux and swallowing disorders, including catheter/wireless (Bravo) pH-monitoring, High Resolution Manometry, Endoscopy and Barium swallow. He continues to publish and collaborate with fellow experts and esophageal units nationally and internationally. He is currently PI in the UK (central site Leuven) of a multi-centre randomised trial comparing POEM with pneumatic dilatation.

He is an active member of the international High Resolution Manometry Working Group, which is responsible for classifying esophageal disorders including the Chicago Classification. He is also a member of the Neurogastroenterology & Motility Committee of the British Society of Gastroenterology and has recently become President of the Association of GI Physiologists (AGIP).

Rami Sweis is actively involved in improving training and Upper GI physiology. He regularly organises and chairs Upper GI Symposia and Hands-on Training in Upper GI physiology in the UK (through AGIP, NGM and at UCLH) and through other societies abroad.

As a member of the Upper GI Endoscopy team at UCLH, Rami Sweis has a particular interest in investigating and managing complex benign and malignant upper GI disorders such as Achalasia (sequential pneumatic dilatation and per-oral endoscopic myotomy; POEM), Barrett’s esophagus (radio-frequency ablation and endoscopic mucosal resection), Gastric dysplasia (submucosal dissection) and upper GI cancer (dilatation, stent and laser).
Results of an Audit of Hydrogen/ Methane Breath Testing for Small Intestinal Bacterial Overgrowth

Steve Perring* and Connor Perring^  
*Poole Hospital Medical Physics Department  
^St George’s Medical School, London

Background

As Anthony Hobson so eloquently described in the last edition of NewWave, the technique of hydrogen/ methane breath testing (BT) for detection of small intestinal bacterial overgrowth (SIBO) is widely used but is notable for the inconsistently of technique used between centres and differences in interpretation of results. As a result the technique is considered by many clinicians to be ineffective due to its poor reliability and accuracy. We wished to review previous studies to see if the test is effective and understand more about the barriers to making this a trusted test.

Method

We reviewed 60 sequential BT studies for diagnosis of SIBO performed between November 2015 and February 2017 at Poole Hospital. We recorded data from the investigation including:

- Symptoms reported during study
- Baseline and maximum breath levels (hydrogen and methane)
- Time to the expected rise in breath levels associated with large bowel fermentation of Lactulose (small intestinal transit time)
- Whether tested primarily for SIBO or as a preamble to carbohydrate malabsorption testing
- Positive for SIBO based on hydrogen or methane?

For those diagnosed with SIBO we interrogated their electronic and paper records in order to establish:

- If the patient had been followed-up subsequent to the investigation?
- If treatment had been given to mitigate SIBO and if so what treatment?
- If the treatment had been successful in reducing symptoms?

Results

1. Diagnosis of SIBO

<table>
<thead>
<tr>
<th>Number of SIBO studies reviewed</th>
<th>60</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number positive for SIBO</td>
<td>23</td>
<td>38%</td>
</tr>
<tr>
<td>Diagnosed with hydrogen</td>
<td>18</td>
<td>78% of +ves</td>
</tr>
<tr>
<td>Diagnosed with methane</td>
<td>4</td>
<td>17% of +ves</td>
</tr>
<tr>
<td>Diagnosed with both hydrogen and methane</td>
<td>1</td>
<td>4% of +ves</td>
</tr>
<tr>
<td>Number due to have carbohydrate malabsorption testing</td>
<td>4</td>
<td>17% of +ves</td>
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2. Treatment of Patients

<table>
<thead>
<tr>
<th>Number of positive SIBO studies</th>
<th>23</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number where subsequent treatment is recorded</td>
<td>21</td>
<td>91% of +ves</td>
</tr>
<tr>
<td>Number treated with antibiotic</td>
<td>21</td>
<td>100% of treated</td>
</tr>
<tr>
<td>Number where post-treatment follow-up is recorded</td>
<td>13</td>
<td>62% of treated</td>
</tr>
<tr>
<td>Number reporting some improvement in symptoms</td>
<td>13</td>
<td>100% of followed-up</td>
</tr>
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<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Times used</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Ciprofloxacin</td>
<td>12</td>
<td>57.1%</td>
</tr>
<tr>
<td>Co-amoxiclav</td>
<td>4</td>
<td>19.0%</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>2</td>
<td>9.5%</td>
</tr>
<tr>
<td>Rifaxamin</td>
<td>1</td>
<td>4.8%</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>1</td>
<td>4.8%</td>
</tr>
<tr>
<td>Augmentin</td>
<td>1</td>
<td>4.8%</td>
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3. Small Intestinal Transit Time

Small intestinal transit time was (mean +/- SD) 104 +/- 40mins

Factors affecting small intestinal transit time

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<tr>
<th>Factor</th>
<th>Spearman’s Coefficient</th>
<th>P-value</th>
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<tr>
<td>Baseline H2</td>
<td>-0.14</td>
<td>0.33</td>
</tr>
<tr>
<td>Max H2</td>
<td>-0.56</td>
<td>&lt;0.001</td>
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<tr>
<td>Baseline CH4</td>
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<td>0.017</td>
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<tr>
<td>Max CH4</td>
<td>0.33</td>
<td>0.020</td>
</tr>
<tr>
<td>Age</td>
<td>0.43</td>
<td>0.002</td>
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Discussion

This study suggests that SIBO is reasonably common in patients with IBS type symptoms 17% of the positive studies were on patients having SIBO investigation as a preamble to carbohydrate testing and with no clinical suspicion of SIBO.

The study confirms the necessity of measurement of methane breath levels over and above hydrogen breath testing in order to avoid false negative results. 23% of positive studies were based on methane production.

Antibiotic treatment was given on all patients reported as having SIBO where records of subsequent treatment were available. The antibiotic used was variable.

All patients treated with antibiotics for SIBO and followed-up with comments on the effectiveness of treatment have reported at least some improvement in their symptoms, which suggests reasonable identification of SIBO with the technique.

The variability of small bowel transit time has considerable implications for diagnosis of SIBO with Lactulose substrate as it is difficult to separate a rise in hydrogen or methane breath level resulting from distal SIBO from the rise resulting from large bowel fermentation of the Lactulose in the context of rapid small bowel transit. In this study 12/23 (52%) of the studies identified as SIBO had estimated small bowel transit time less than 90 minutes. 9/37 (24%) of studies reported as normal on SIBO studies also had estimated small bowel transit time less than 90 minutes. Clearly assessment of presence or absence of SIBO has been based on more than a strict interpretation of a set of criteria as detailed below:

SIBO = rise in breath hydrogen >=20ppm or methane >=10ppm occurring within 90 minutes of ingestion of the Lactulose.

Typically clinical judgement has been based on other factors in addition to the criteria above such as presence or otherwise of contemporaneous symptoms and the shape of the breath concentration/time graph.

Conclusions/ Take Home Messages

- Breath testing for SIBO does appear effective
- Methane measurement is essential if miss-diagnosis is to be avoided
- There is a need for national consensus on antibiotic treatment for SIBO
- The variability of small bowel transit makes interpretation of Lactulose substrate breath testing complex and prone to error
This was a very illuminating meeting, with a galaxy of the great and the good in GERD there to offer opinions on the future of GERD diagnosis and treatment. Some interesting new concepts were offered and some controversial opinions expressed.

Two new metrics were being suggested as of considerable value to assessment of GERD. Prof Edoardo Savarino of Padua, Italy was particularly an advocate of these measures.

Post-Reflux Swallow Induced Peristaltic Wave Index (PSPW Index). PSPWs are the (unconscious) peristaltic waves that occur following a reflux event after the initial reflux flow has been swallowed down. These are suspected to result from chemical stimulation of the oesophageal lining and are largely responsible for clearance of the acid reflux residue on the oesophageal lining. The index is a measure of the effectiveness of this clearance mechanism, so a low index might be associated with increased reflux.

Mean Nocturnal Baseline Impedance (MNBI) is a measure of the stable intra-luminal impedance, using the nocturnal period as it is period with a low rate of peristaltic wave related changes in impedance. It is suggested that this metric is also closely related to reflux.

Neither of these metrics are automatically calculated as yet by commercial software.
Prof Frank Zerbib from Bordeaux, France also advocated the use of PSPW Index and MNBI as measures of reflux. He was concerned about the poor effectiveness of pH measurement of pharyngeal reflux, particularly the Restech system.

Prof Michael Vaezi from Nashville, USA suggested that baseline mucosal impedance is also potentially a measure sensitive to the presence of eosinophilic oesophagitis.

Prof Radu Tutuian from Bern, Switzerland talked about manometry and GERD. He advocated a range of swallow provocations on top of the normal 5ml water swallows, including multiple-rapid swallows, free swallowing and semi-solid swallows such as fruit puree. He noted that “ineffective oesophageal motility” as defined by Chicago Criteria is common in GERD and probably not significant. It is possibly a consequence of mucosal inflammation. He proposed that the quality of peristalsis after multiple rapid swallows is a good indication of risk of late dysphagia following fundoplication. He also suggested that the quality of contraction following 200ml free swallowing is important as the volume being ingested is similar to that of a meal. Integrated Relaxation Pressure (IRP) is also important in predicting post-fundoplication symptoms, but most effective if IRP is assessed following 200ml free swallowing.

Prof Andre Smout from Amsterdam, Netherlands was talking about the poor consistency between symptom index (SI) and symptom association probability (SAP). The reproducibility of both metrics is poor. He suggested that extending the study over 2 days would potentially increase yield significantly.

As expected from a conference in Lyon, the food was wonderful and it was great to have coffee with Prof Pandolfino!

Budding Reviewers

If you attend a meeting and wish to review a presentation at that meeting in a future edition of NewWave, please contact the NewWave editor (steve.perring@poole.nhs.uk)

Help-out the rest of us who did not manage to get to the meeting
A reminder of the AGIP Bursary Scheme:

The following bursaries are still open for application:

1. **Bursaries for BSG 2018, Liverpool**

   Up to 5 bursaries will be offered of up to £300 each. The grant will be conditional on submitting an abstract to BSG and writing a review article for a future edition of NewWave reviewing a talk at the meeting.

2. **Bursary for a European conference in 2018 (most likely EUG 2018, Vienna)**

   One bursary will be offered up to a maximum of £750. The grant will be conditional on an abstract being accepted for the meeting and writing an extended (3-4 page) review of the conference for NewWave.

If you are interested in applying please submit an expression of interest to Steve Perring before 1st March 2018. You can contact him at:

   **Steve.perring@poole.nhs.uk**

You do not have to have all the elements in place by this date, but will be expected to have a draft proposal.
Consultation: Promoting professionalism, reforming regulation
Response from the Registration Council for Clinical Physiologists

About the Registration Council for Clinical Physiologists (RCCP)

The RCCP maintains the voluntary register for healthcare professionals across the disciplines of audiology, cardiac-physiology, gastrointestinal physiology, neurophysiology, respiratory physiology, and sleep physiology.

There are approximately 6,000 practitioners on the RCCP’s register. This does not represent the entirety of the Clinical Physiology workforce employed within the NHS.

The RCCP welcomes the Department of Health’s decision to consult on current healthcare regulation and regulatory structures. The RCCP believes that any reform of healthcare regulation must include an assessment as to the need to extend statutory regulation, such as those across clinical physiology disciplines to ensure consistency of approach to regulation and to minimise any potential risk to patients. The RCCP firmly believes the current system of assured voluntary registration cannot, in the case of clinical physiologists, provide sufficient levels of public and patient protection.

Consultation questions and RCCP responses

Do you agree that the PSA should take on the role of advising the UK governments on which groups of healthcare professionals should be regulated?

Yes. The RCCP believes the PSA is best positioned to assess the need for regulation of healthcare practitioners based upon criteria set out in the PSA’s paper titled *Right Tough Assurance: a methodology for assessing and assuring occupational risk of harm.*

What are your views on the criteria suggested by the PSA to assess the appropriate level of regulatory oversight required of various professional groups?

The RCCP believes the criteria set out the PSA (i.e. a two-stage process assessing evidence of risk of harm and then wider external policy factors) represents a sensible and appropriate means of assessing the level of oversight required by various professional groups.

The RCCP is currently in the process of obtaining PSA accreditation, and a significant factor in the decision to seek such accreditation is the criteria set out in the PSA paper *Right Touch Assurance: a methodology for assessing and assuring occupational risk of harm.* The RCCP believes these criteria enables a forward-looking assessment of the possible risks to patients and, consequently, the level of oversight required by professional groups – whether that be a system of assured voluntary registration or statutory regulation.
The RCCP does not believe that every healthcare professional or practitioner should be subject to statutory regulation, but that this should be in place for those practitioners whose roles present significant potential risks to patients’ safety and wellbeing. It considers the current system of voluntary registration is insufficient in the case of clinical physiologists.

Do you agree that the current statutorily regulated professions should be subject to a reassessment to determine the most appropriate level of statutory oversight? Which groups should be reassessed as a priority? Why?

The RCCP contends that a review should be made not only of statutorily regulated professions but also of those professions currently voluntarily regulated, so that a more consistent approach can be obtained. Healthcare is delivered by teams of practitioners with a mix of registration arrangements based on custom and practice rather than evidence. A systematic review of voluntary registers would ensure that registration arrangements were appropriate and robust. It would seem an anomaly, for example, that an educational psychologist is statutorily regulated but clinical physiologists, who have direct patient contact (including vulnerable adults and children) and may carry out invasive procedures are not. There is also the anomaly that Hearing Aid Dispensers and Clinical Scientists in Audiology are statutorily registered with the Health and Care Professions Council (HCPC), Audiologists who comprise the bulk of the workforce, are voluntarily registered. All three professionals perform procedures related to the assessment and rehabilitation of hearing loss. This creates the possibility of unsafe practitioners moving from one role to another and continuing to practice in an unregistered capacity.

Whilst a system of assured voluntary registers offers some benefits, the RCCP believes that it is insufficient for practitioners across the disciplines of clinical physiology, and that statutory regulation would offer greater patient safety and reduction of possible harm.

Clinical physiologists perform procedures, tests and investigations critical to patients’ diagnosis and treatment. Included within these (albeit an indicative and not comprehensive list) are lung function tests, endoscopies, cardiac ultrasound (Echocardiogram) and electroencephalograms (EEGs), Clinical physiologists will also monitor and modify technologies, such as cardiac pacemakers and breathing equipment (continuous positive airway pressure (CPAP) and non-invasive ventilation).

In 2003 the Health Professions Council (now HCPC) used its discretionary powers under the Health and Social Work Professions Order (2001) to recommend to the Secretary of State for Health that clinical physiologists be statutory regulated. This was following an assessment against published criteria, including the potential harm to the public posed by the clinical physiologist profession.

In 2015 the HCPC provided further information to a Health Select Committee about the professions it had previously recommended for regulation, including Clinical Physiologists. [http://www.hcpc-uk.org/assets/documents/10004E02Statutoryregulationoffurtherprofessions-enclosuretoLettertoHealthCommittee18032015.pdf](http://www.hcpc-uk.org/assets/documents/10004E02Statutoryregulationoffurtherprofessions-enclosuretoLettertoHealthCommittee18032015.pdf)

The RCCP provided evidence for the submission. This evidence included instances where patients were put at risk by clinical physiologists and where these risks – and the risk of future occurrence – may have been mitigated by the greater protection afforded by statutory regulation, rather than voluntary regulation. The primary risk from voluntary registration is where complaints have been raised against clinical physiologists who are either not registered with RCCP or then remove themselves from the register as well as
refusing to participate in any disciplinary procedures. This risk is compounded by the fact that voluntary registers (unlike statutory registers) have limited authority and cannot compel complainants, employers or others to give evidence as part of an investigation or hearing.

In 2016 further evidence of serious failings in care by clinical physiologists was provided via an anonymous survey of RCCP registrants. Whilst anecdotal, these accounts have included examples where patients suffered potentially fatal hypertension as a result of errors in the administration of medication; and a patient dying as a consequence of mis-diagnoses during routine echocardiogram investigations. Many of these concerns related to the employment of locums, with locum contracts being terminated with immediate effect without the implementation of any investigation or disciplinary process. Whilst recognising that errors may always occur, the RCCP believes that statutory regulation would better allow effective action against those professionals who fail to meet minimum standards of care and so ensure greater public protection.

In 2017 research by the respected ComRes market research company found that in a survey of over 2,000 members of the British public, approximately two-thirds of respondents would expect practitioners undertaking the work performed by clinical physiologists to be subject to statutory regulation.

What are your views on the use of prohibition orders as an alternative to statutory regulation for some groups of professionals?

The RCCP believes that following an assessment of risk by the PSA, such orders could be appropriate for some sectors of the workforce, such as those working as care assistants in care homes.

Do you agree that there should be fewer regulatory bodies?

Yes. Any means to simplify regulation and so make the process clearer for the public and patients is to be welcomed.

What do you think would be the advantages and disadvantages of having fewer professional regulators?

Fewer regulatory bodies would bring greater efficiency and consistency as well as delivering cost benefits. It would also simplify the regulatory landscape and so be easier to be understood by all stakeholders. A possible disadvantage is that a single regulator may lose sight of the unique risks posed by different professions. It is important that quality assurance is appropriate for the diverse range of professions covered by the regulators.

Do you have views on how the regulators could be configured if they are reduced in number?

No.

Do you agree that all regulatory bodies should be given a full range of powers for resolving fitness to practise cases?

Yes.

What are your views on the role of mediation in the fitness to practise process?
Mediation may have a place in, for example, complaints regarding fees or premises. However, many fitness to practice cases would not seem amenable to mediation. The mediation pilot run by the HCPC received very little uptake despite being promoted and the pilot period extended. The RCCP has recently appointed a Professional Affairs Officer with experience of mediation and it will be interesting to see if this approach is useful.

**Do you agree that the PSA’s standards should place less emphasis on fitness to practise performance and consider the wider performance of the regulators?**

Yes. Whilst fitness to practice is one aspect of regulation the ability to deal with potential problems ‘upstream’ by, for example, addressing education and ongoing continual professional development is also important. Healthcare delivery is becoming increasingly complex, involving a wide range of health and social care professionals in many different sectors, with increasing risks to patient safety. Regulation has to be able to respond to, and influence, such developments by ensuring a focus on patient safety. It can only do this by having methods of assessment that span care pathways and consider longer term health outcomes.

**Do you agree that the PSA should retain its powers to appeal regulators’ fitness to practise decisions to the relevant court, where it is considered the original decision is not adequate to protect the public?**

Yes

**Do you think the regulators have a role in supporting professionalism and if so how can regulators better support registrants to meet and retain professional standards?**

Professionalism is a developing and complex concept. Regulators are potentially in a strong position to commission research to help explore what it means, how it is generated, and how it is translated into practice. This could also help identify areas of concern and enable the development of recommendations for education and training. This could also lead to a wider discussion on the systemic support required for professionals to meet required standards, for example employers ensuring adequate time for CPD activities.

**Do you agree that the regulators should work more closely together? Why?**

Greater collaboration could result in greater consistency of approach leading to enhanced patient safety. It would also enable the sharing of resources such as back office functions. A single online register would be simpler and more accessible for the public.

**Do you think the areas suggested above are the right ones to encourage joint working? How would those contribute to improve patient protection? Are there any other areas where joint working would be beneficial?**

Yes. Greater collaboration would enable an increased understanding of factors that lead to failings in care across complex pathways and systems. A single register would have advantages for patients, employers and colleague, providing a one-stop shop for checking all healthcare professionals are registered, rather than having to work out which ones are regulated and by whom, then accessing several websites. The HCPC has shown that it is possible to operate with generic standards across a range of professions, with the addition of specific profession-related standards as necessary. It should be possible to replicate this approach across all healthcare professionals. A single adjudicator would also mean there could be a consistency of approach, for example when a range of healthcare professionals are involved in the same incident resulting in an investigation.
Do you agree that data sharing between healthcare regulators including systems regulators could help identify potential harm earlier?
Yes

Do you agree that the regulatory bodies should be given greater flexibility to set their own operating procedures?
Yes.

Do you agree that the regulatory bodies should be more accountable to the Scottish Parliament, the National Assembly for Wales and the Northern Ireland Assembly, in addition to the UK Parliament?
Yes this would assist in a uniform approach across the UK, but care must be taken to ensure that variability in policy decisions and the slowing down of decision making to achieve consensus is not introduced.

Do you agree that the councils of the regulatory bodies should be changed so that they comprise both non-executive and executive members?
Yes. This would bring the councils into line with NHS and other organisations within the health arena which have unitary boards.

Do you think that the views of employers should be better reflected on the councils of the regulatory bodies, and how might this be achieved?
Yes. This could be achieved by ensuring that at least one of the Council members is able to reflect the views of employers (though not act as a representative). The Council could also ensure it holds regular stakeholder events with employers and canvases their views so as to inform decision-making.

Should each regulatory body be asked to set out proposals about how they will ensure they produce and sustain fit to practise and fit for purpose professionals?
Yes

Should potential savings generated through the reforms be passed back as fee reductions, be invested upstream to support professionalism, or both? Are there other areas where potential savings should be reinvested?
Both

How will the proposed changes affect the costs or benefits for your organisation or those you represent?

- an increase
- a decrease
- stay the same

Please explain your answer and provide an estimate of impact if possible.

If the PSA were to carry out a review of regulation and to make recommendations as to which professions should be statutory or voluntary regulated, this would have an obvious
impact on the professions concerned. If clinical physiologists were recommended for statutory regulation this may cause an increase in registration costs from the current annual renewal fee of £40. However the RCCP believes that the majority of its registrants would welcome statutory regulation, which has been a longstanding organisational aim. For those clinical physiologists not currently registered then this would be a new cost.

How will the proposed changes contribute to improved public protection and patient safety (health benefits) and how could this be measured?

A streamlined system of professional regulation, which includes a risk assessment of all healthcare professionals currently regulated (voluntary or statutory) should provide a more consistent approach to regulation and so improved patient safety. The proposed system should also enable the PSA to respond to changes in the workforce as new professions emerge and existing ones take on new responsibilities and roles.

Do you think that any of the proposals would help achieve any of the following aims:

- Eliminating discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010 and Section 75(1) and (2) of the Northern Ireland Act 1998?
- Advancing equality of opportunity between persons who share a relevant protected Characteristic and persons who do not share it?
- Fostering good relations between persons who share a relevant protected characteristic and persons who do not share it?

If yes, could the proposals be changed so that they are more effective?

If not, please explain what effect you think the proposals will have and whether you think the proposals should be changed so that they would help achieve those aims?

It is not clear how these recommendations in of themselves would help achieve these aims, rather it is how they are implemented which will impact on issues of equality.

Contact

For further information about any comments in this submission, please contact:

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