Welcome to the second e-newsletter of NewWave. We have had some good feedback from the first edition. We still however need articles and featured abstracts so contributions welcome.

I am sure you will all join us in congratulating Patricia Vales who has been awarded an MBE for services to Healthcare Science. The investiture was at Buckingham Palace and the award was given to her by Prince Charles. Patricia explains further:

I was able to get an extra ticket so that all of my family could attend. It was quite a spectacular event and it was good to meet and talk to the other recipients. There was such a mix of backgrounds and variety of fields that had won awards that it made me both humbled and proud at the same time.

I received my initial training as a GI Physiologist at Mr John Bancewicz’s unit at Hope Hospital under the legendary Margaret Marples and at Dr Robert Heading’s unit in Edinburgh under Anne Pryde. I was one of the first members of AGIP, attending inaugural meetings in Salford led by John Lennard-Jones and over the years was privileged to help shape our Education and Training pathways.

I was our original representative on RCCP and am due to retire from that council at the end of 2012 as Kathy Noble and Elisa Wrightham are now
taking over the reins. I am also an HPC Partner assessing oversees applications to the Clinical Physiology modality and will keep this position for another couple of years until the new Academy of Healthcare Science has been established.

As Chair of the Accreditation and Education Committee I was asked by the Chief Scientific Officer, Professor Sue Hill, to contribute to the Physiological Sciences arm of the Healthcare Science workforce initiatives of the Department of Health.

It would have been impossible to do this without the help of the members of AGIP Council and the Accreditation and Education Committee. In particular Dr Bob Heading, Prof Graeme Duthie, Dr Jo Barlow, Lynne Smith, Graham Buckton, Sarah Douglas, Dr Daniel Sifrim and Dr Kevin Haylett who all sat through some very long seminars and scripted our contributions to various DH publications.

There are so many of the members of AGIP who contributed to me being awarded the MBE that I do sincerely feel that this award rightly belongs with AGIP and is a reflection of the importance of GI physiologists in the healthcare workforce. Thanks to everyone else’s hard work it was a sinecure for me and thoroughly enjoyable and I recommend membership of AGIP and the council to everyone.

G.I. Manometry disinfection made simple

Benefits of using Stella Pulse Disinfection System and Tristel chlorine dioxide based Fuse for Instruments include:

- Quick turnaround of instruments allows faster patient throughput
- Significant cost savings in comparison to a fully automated washer disinfector
- Safety and peace of mind for Doctors, Nurses, Infection Control Officers and Patients

- Fast, safe and convenient decontamination of solid state catheters
- Recommended by catheter manufacturers, including for use with high resolution manometry catheters
Membership of HPC for overseas (Irish) members

Patricia Vales MBE, FAGIP

The Health Professions Council (HPC) currently accepts applications onto the Clinical Scientist Register from applicants trained and working abroad*. This may be of particular interest to AGIP/BSG members from the Irish Republic working as GI Physiologists who may be interested in working in the UK or who may wish to be registered for personal accreditation reasons.

The Clinical Physiology Modality is probably the most suitable although Physiological Measurements Modality is also available. There is a substantial cost involved in processing this type of application which is non returnable and if successful there is then the cost of registering.

Information on this pathway is available at the HPC web site [www.hpc-uk.org](http://www.hpc-uk.org) or by writing directly to HPC at Park House, 184 Kennington Park Road, London, SE11 4BU

Due to the expense involved it would be advisable to write to HPC outlining qualifications and level of current responsibilities both clinical and scientific and seeking advice on likely acceptance as these enquiries are usually forwarded to one of their Partners specialising in Clinical Physiology. This would then be a good indication of whether or not to proceed with an application.
Although there has been no indication from HPC that these pathways to registration are to be discontinued in the near future there may well be changes due to the introduction of Modernising Scientific Careers (MSC) in the UK with new Healthcare Training Pathways. As part of these changes AGIP is phasing out the BSc training programme in favor of a graduate Scientific Training Pathway. Registration at output of this programme will be equivalent to the current Clinical Scientist training output.

It may therefore be a good time for anyone interested in applying for posts in the UK to investigate registration with HPC.

* This pathway is not available to GI Physiologist trained and currently working in the UK.

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Report on the 1st Advanced Neuro-Gastro Diagnostic training day at the Royal Society of Medicine - Thursday 26th January 2012

**Pills and Probes – New Insights into Lower Gut Function**

**Dr Anthony Hobson PhD – Facility Director, Neurogastroenterology Diagnostic Centre, The Princess Grace Hospital, London UK**

I have to confess that after 13-years or so of working in a busy GI Physiology department at Hope Hospital, by 2004, I was pretty bored. We had certainly moved on from GRASS polygraph chart recorders to digital manometry systems over that time but essentially the technology hadn’t really moved on. I remember doing a quick audit on our oesophageal manometry results which showed that 90% of our studies were reported as either normal or as a non-specific motility disorder which I found to be really quite unsatisfying as I was sure we were missing allsorts of important information because of the limitations of the technology.

In the summer of that year I attended the first Neurogastroenterology Summer School held in Germany run by the European Neurogastroenterology faculty led by Dr Paul Enck from Tubingen. This was a fantastic week long course held in a 14th century castle in the German countryside and was attended by clinicians, physiologists, basic scientists and scientists from the pharmaceutical industry (about 30 in total). We heard lectures from world experts in various fields, were put together into project teams to work on difficult problems and had the opportunity to present some of our own research to the rest of the group and faculty.

One fellow attendee on this course was Mark Fox who was presenting some of the early high resolution oesophageal manometry showing there was so much more that we could get from our clinical studies compared to what we currently had. This was just one example of the direction in which the field was heading and I left the week feeling somewhat rejuvenated and invigorated with the whole area. Knowing that there was so much in the pipeline that was going to ‘revolutionise’ our understanding of neurogastroenterological conditions and help us to provide better diagnoses and management of our patients helped me overcome my previous malaise.

The point of this somewhat rambling preface is to set into context the motivation behind setting up this recent training symposium in London some 7-years later. Over this period many of these research tools have now translated into clinical practice and the technology is moving forward at a rapid pace and yet the training and support infrastructure to help professionals in our field to keep up with these advances has been lacking. As everyone’s busy clinical services have got busier, it seems that it has been harder to keep the community together and many units exist as ‘islands’ with the only interaction being the occasional chance meeting at the BSG or smaller regional events.
Having spent a 3-year sabbatical in the pharmaceutical industry, when I returned it was clear that there had been little guidance from national bodies and confusing messages from government about the long term training structure in neurogastroenterology. When I was asked to do a couple of training events for various equipment companies the feedback was that everyone was very keen to modernise their services but felt there was no where they could turn to for guidance, support and training and this was holding them back from embracing the advances in new diagnostic techniques that are so crucial to improving our services. So we decided to contribute in some small way by holding the 1st Neurogastroenterology training workshop at the Royal Society of Medicine in London as part of a new initiative to increase the number of training events available to evaluate some of the new advances in our field. We decided to look at two new techniques for assessing lower gut function, High Resolution Ano-rectal Manometry (HRaM) and the Wireless Motility Capsule (WMC).

The speakers were Professor Charles Knowles and Dr Mark Scott from the Royal London Hospital, Dr Jack Semler from SmartPill Corporation (the manufacturers of the WMC) and I spoke about the clinical utility of the WMC and chaired the sessions. The format was designed to provide a clinical background to the utility of diagnostics in assessing diseases of the lower gut, provide an overview of the old and new techniques, have a practical demonstration of the WMC and finish with case studies and discussion. The meeting was very well attended with delegates coming from such far flung places as Denmark and Hull and the venue was excellent situated in the heart of the West End of London. Access to all of the slides from the presentation can be gained by following the instruction at the end of the article.

1 - Overview of the use of physiological assessments in Colorectal disorders – Professor Charles Knowles – Royal London Hospital.

The newly anointed Professor Knowles was kind enough to start the day off with an excellent presentation which explained where physiological assessments fit in the patient pathway for conditions such as faecal incontinence and constipation. Starting with a description borrowed from Anton Emmanuel which compares defaecation to a tube of toothpaste (got to be full, have to know that it is full, got to squeeze it, got to take the lid off, got to put the lid back on), he spoke about the different stages of the whole process in the context of normal and abnormal physiology.

In addition to taking a detailed clinical history and examination of the patient, he described how each of the different diagnostic techniques could be used to determine structural integrity (e.g., endo-anal ultrasound) as well as function (proctography and manometry). Importantly, in the context of clinical decision making, he showed the importance of clinico-radiological-physiological correlation in confirming the diagnosis in different types of faecal incontinence patients. There was a reference to the International Consultation on Incontinence (ICI) guidelines from 2009 which provide a nice schematic diagnostic and treatment pathway and also provided an overview of current treatment options. He then provided a similar overview for chronic constipation.

In his summing up he concluded that ano-rectal / colonic physiological testing adds value in guiding management, they are well established for faecal incontinence and constipation which is not responding to conventional treatment (even if didactic scientific evidence is currently incomplete) and that the limitations of existing measures (i.e., accuracy and acceptability) may be addressed by advances in technology. This led is nicely into our second presentation of the day looking at one of these new technologies, SmartPill’s Wireless Motility Capsule.

2 - SmartPill: Wireless Motility Capsule (WMC) – Historical perspectives and clinical validation studies – Dr Jack Semler PhD, Chief Technology Officer, SmartPill Corporation, Buffalo, USA.

Jack kindly offered to come over to the UK for what was the first time that the SmartPill GI
Monitoring System had been available for scrutiny outside of the US. The device achieved CE mark in the EU in the third quarter of 2011 meaning that it is now available for clinical use in the UK. In the US, the WMC has been used in over 9000 patients and there are over 15 publications in the literature describing some of the validation studies that have been carried out as part of the regulatory approval process.

From a historical perspective, Jack explained that motility capsules have been in development since the 1950’s with the first papers appearing in GUT in 1963. Whilst in the past these were tethered and retrievable, the WMC is a single use device in the form of an ingestible telemetric capsule that detects changes in pressure, temperature and pH as it transits through the gastrointestinal (GI) tract. The changes in pH allow measurement of the transit time of the WMC through different GI compartments (stomach, small intestine and colon) whilst quantifying gut contractility. It is approved for use in the assessment of gastroparesis (slow gastric emptying), constipation (slow bowel transit) and there are on-going studies in the US assessing it’s utility in other conditions such as Irritable Bowel Syndrome (IBS) and paediatric (over 12’s) populations.

The WMC is about the same size as the PillCam which is used for capsule endoscopy and therefore patients with swallowing difficulties should be excluded. In addition, there are several other contra-indications for use such as recent GI Surgery, co-existent electro-mechanical devices and evidence of a small bowel stricture, for example. Because large, non-digestible particles are only emptied in the fasting state in conjunction with the onset of a migrating motor complex (MMC), a standardised test meal is given prior to capsule ingestion (SmartBar – a fruit flavoured cereal bar of known nutritional and calorific content). Once the test meal is consumed, the capsule is activated (using a powerful magnet situated in an activation chamber) and the patient swallows the capsule with around 150ml of water.

![Figure 1.](image)

Figure 1 shows a screenshot of the data obtained via the capsule during the gastric emptying phase of the study (pH is displayed in green, pressure in red and temperature in blue). Immediately after ingestion the gastric pH is around 4 as the gastric acid is buffered by the test meal. Once the meal begins to empty, the pH falls until it reaches fasting levels at around pH 1.5. Once the stomach is in the fasted state, MMC’s begin to appear as clusters of contractions and it is those contractions...
that push the WMC through the pylorus into the duodenum.

This is very clearly seen as the pH rises sharply to around 6.5 in the proximal duodenum. In 95% of healthy subjects, the WMC empties within 5-hours of ingestion giving a clear cut-off for gastroparesis. Patients are asked not to eat for 6-hours following the test to allow the stomach to empty the test meal and establish MMC activity so the capsule can be emptied. If the WMC does not empty by the time the patient eats a second meal, then the fed pattern is re-established and the capsule will be retained in the stomach. In most cases if this occurs, the WMC usually leaves the stomach during the night-time period when the patient is asleep.

In the small bowel, the pH gradually rises as the WMC moves distally towards the terminal ileum where the pH is the highest in the GI tract (around pH 7.5-8). Normal small bowel transit time is <6.5 hours and once the WMC reaches the ileo-caecal junction (ICJ) and increase in contractile activity can often be seen prior to movement through the ICJ (figure 2). The pH in the caecum is more acidic than in the colon (usually a drop of about 1.5 units) as bacteria breakdown carbohydrates during the fermentation process producing short chain fatty acids (SCFA). Jack was able to show us a nice video clip from a study carried out by Mark Scott where the WMC was filled with a scintigraphic contrast agent and imaged in real-time as it moved through the ICJ with the corresponding pH changes recorded simultaneously, thus validating this physiological landmark.

**Figure 2.**

![Increasing pH profile as WMC moves from the duodenum to the terminal ileum](image)

When the capsule reached the colon, the pH once again gradually rises as it moves distally reaching a plateau in the recto-sigmoid region. The WMC is expelled when the subject has a bowel movement. The patient is asked to wait for around 1-minute following the bowel movement before flushing the toilet. This allows the temperature sensor on the WMC to detect the fall in temperature as the capsule exits the body confirming the test is finished. This has a safety element confirming the WMC has not been retained in the body. Once the patient has flushed the toilet, the box will display a cross if the capsule has been passed and the patient can turn the box off ready for return to the department. The test may last 1-4 days, but longer in constipated patients. If the WMC is not passed by day 4, it is recommended that they come back to the department and
charge the box up, they can then take a mild laxative just to help things along. The capsule can keep transmitting for over 10-days, but after this an x-ray would be needed to confirm expulsion.

Jack finished by showing how the technique has been extensively validated against current gold standard methodologies (gastric emptying scintigraphy and radio opaque colonic marker studies) and is sensitive in picking up changes in GI transit caused by pharmacological and nutritional interventions. There was a tremendous amount of data to take in from this presentation but the take home message was that this is an extremely useful diagnostic tool which is patient friendly and uses much less resources compared to existing scintigraphic and manometric alternatives. This setup the afternoon practical demonstration and clinical utility talks nicely but before that it was Dr Mark Scott’s turn to describe another new and exciting technology, high resolution ano-rectal manometry.

3 - New insights into the mechanisms of ano-rectal dysfunction using high resolution ano-rectal manometry – Dr Mark Scott – Royal London Hospital.

Mark began his talk by putting the role of ano-rectal manometry in the context of the myriad other diagnostic tools at the disposal of the GI Physiologist. Whilst some of these techniques are fairly well validated there remains little consensus on how data is acquired and analysed meaning that standardisation which would allow inter centre comparisons of clinical data is mostly not possible which is problematic. He went on to say that ano-rectal manometry is most useful when used in conjunction with radiological techniques that provide information about the structure of the ano-rectal musculature. He outlined the different measurements that are commonly recorded including resting and squeeze pressure, recto-anal inhibitory reflex, cough reflex and defaecatory manoeuvres.

In terms of what high resolution ano-rectal manometry may bring to the table, he showed the impact that HRM has had on the oesophagology field quickly becoming the gold standard and leading to an explosion of research articles since it’s inception back in 2003. Currently there are only 2 HRaM articles in press but the scope for this new technique to become the new gold standard was discussed as we got to see how HRaM provides different insights and intuitive visualisation of physiological functions for both the physiologist and patient. What was particularly impressive was the extra certainty that HRaM gives you when recording data as artefacts that commonly afflict conventional manometric acquisition (such as movement artefacts) are eradicated by the use of these more extensive sensor arrays.

He then talked about some of the novel findings that we have seen in our laboratory at the Princess Grace Hospital. One of the interesting features that HRaM has enabled us to look at in more detail is the role of sphincter relaxation in patients with faecal incontinence. The mechanisms of faecal incontinence (FI) are numerous and can include damage to the external anal sphincter, poor rectal sensation and neurological damage. One of the simple ways to test neuromuscular integrity in the anal canal is to measure the cough reflex. On coughing there is a sharp rise in intra-rectal pressure which is accompanied by a reflex contraction of the external anal sphincter. The strength of this contraction has to be sufficient to ensure the maintenance of continence. If the sphincter has been damaged as in obstetric injury or if there is a problem with the extrinsic innervation to the sphincter, this reflex response is compromised, and faecal leakage can occur. Using HRaM, it is possible to easily visualise this recto-anal pressure gradient using spatiotemporal colour plots (Figure 3a).
However, in addition to assessing the contractile response of the sphincter, we have also noted that in many FI patients, a transient loss in anal sphincter tone is observed following the reflex contraction which can persist for several seconds (Figure 3b). Proctographic studies have confirmed that faecal leakage can occur during this period of ‘transient’ anal sphincter relaxation (‘TASR’s) making this phenomenon a potentially important and as yet undescribed mechanism of FI. In addition to observing TASR’s following a cough, we have also observed TASR’s spontaneously and following squeeze manoeuvres in FI patients.

Internal anal sphincter tone comprises myogenic and neurogenic components the regulation of which contributes to both successful evacuation and maintenance of faecal continence. Sympathetic and parasympathetic nerves regulate the neurogenic component with Nitric Oxide and VIP thought to be important in the recto-anal inhibitory reflex whilst neurohumoral mediators such as angiotensin II contributing to increasing basal tone. It is well known that distension of the distal rectum induces the neural mediated recto-anal inhibitory reflex response. However, if these reflex relaxations occur at inappropriate moments, then it is feasible that faecal leakage would occur.

Using conventional, low resolution anal manometry, any such reduction in the anal sphincter tone is difficult to recognise as the single point sensors often move slightly during the manoeuvre slipping out of the high pressure zone. The increased spatial resolution of HRaM allows you to monitor such movement artefacts with greater sensitivity giving greater reassurance of the physiological validity of manometric observations. Just as high resolution oesophageal manometry has provided us with greater sensitivity in observed pathophysiological events such as transient lower oesophageal sphincter relaxations in patients with reflux disease, so HRaM may well provide us with new insights into mechanisms of evacuatory dysfunction and FI.

Finally, Dr Scott discussed how one of the very important aspects that HRaM may bring to the table is the chance to standardise acquisition and analysis across centres. This may finally bring together a consensus opinion across the community in a manner similar to that which has been so successfully achieved with the Chicago Classification in the oesophageal field.

4 – Technical demonstrations and case studies – Dr Anthony Hobson and Dr Mark Scott
After a fantastic lunch in the spectacular atrium at the RSM, a rather soporific bunch returned to the Wimpole Room for the afternoon session. In order to give those over taxed brains a bit of light relief, Jack and I did a live demonstration of the SmartPill system setup and acquisition. One of the
nice features of the system is that once the WMC is activated there is the option to enter into a live monitoring mode so that you are certain that the capsule is functioning properly both prior to and, if required, after the patient has ingested it. As with all live demonstrations, there were a couple of small hiccups not least when Jack poured the calibration buffer into my glass of water which I would have readily drunk if it wasn’t for a vigilant Dr Steve Middleton from Addenbrooke’s who was in the front row!

Following the practical demonstration we went through how to analyse the tracings. Whilst measurement of transit times is fairly straight forward, we showed how the analysis can be anchored around known certain gut regions by measuring contractility at given time points prior to and following passage of the WMC through the pylorus, ICJ and prior to capsule expulsion. This allows characterisation of antral, duodenal, ileal, caecal and recto-sigmoid contractility and he showed normative data from various clinical trials which is now being used to compare to patients with various symptomatic profiles. We also saw some of the technical issues that may lead to signal loss if patients don’t keep the data receiver within range during the study, something that occur especially during the night time period.

**Case studies:** For the final session of the day, Mark and I each presented 5 cases of typical patients attending their unit where these new technologies have been useful in adding diagnostic value to the understanding of their underlying pathophysiology. Mark began with two examples of patients with faecal incontinence and leakage showing nicely how the high resolution ano-rectal catheter can be placed in one position whilst detecting the full range of physiological responses. The images clearly showed virtually absent resting tone with poor cough reflex and squeeze contractions in subject 1. This was supplemented by endo-anal ultrasound and proctographic measures to provide a comprehensive assessment of the mechanisms of faecal incontinence in this patient (i.e, poor manometric tone was related to sphincter damage and leakage on the proctogram especially during stress manoeuvres such as coughing).

In case number 4, an excellent image showing an absent recto-anal inhibitory reflex in a patient with a long standing history of difficult defaecation was displayed. Even with sequential and rapid distension with 60ml aliquots up to a maximum of 420ml, no relaxation of the anal musculature was seen (figure 4). The final case showed a patient with dysynergic defaecation (DD) prior to and following biofeedback. On of the impressive features of HRaM is just how intuitive the display is both for the operator and the patient which really helps to reinforce the correct behaviours during biofeedback sessions. In this example it was shown how the patient progressed from type IV DD (ineffective evacuatory force) to normal evacuation over 4 sessions of biofeedback. The ability to see the anal muscles relaxing whilst the intra-rectal pressures were increased greatly facilitated the learning process and also produced some very nice images (figure 5).

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**Figure 4.**

![Image of anal sphincter tone and balloon channel analysis](image-url)
I then presented five very different cases of patients that presented with quite similar symptoms (usually overlapping upper and lower GI symptoms such as nausea, epigastric pain, bloating, constipation, diarrhoea and various post prandial symptoms). Whilst the WMC can detect rapid, normal or delayed transit through the gut compartments, I showed some of the more nuanced analysis techniques which take greater account of the contractility profiles and pH changes around certain anatomical landmarks. It was clear that there were patients with similar symptoms that had contractile response which covered the entire spectrum from hypo to hyper-contractility and this was not always correlated with transit times. This is important as the underlying pathophysiology and subsequent treatments strategies in these patients may be totally different.

Some of the most interesting findings were around the ileo-caecal junction. In some patients, there was a very large drop in pH of around 2.5 units (normal is around 1.5 units) as the WMC passed through the ICJ. As this drop in pH reflects production of short chain fatty acids following fermentation of carbohydrates by colonic bacteria, this large drop may reflect a degree of excessive fermentation in the proximal colon.

Terminal ileal contractility is invariable greater than that seen in the caecum in normal subjects allowing passage of material in an antegrade manner through the ileo-caecal valve. However, in some patients, this contractile gradient is reversed with more activity seen in the caecum. As the ICJ is the one true ‘valve’ in the GI tract (i.e., the direction of movement through the ICJ depends on which side has the highest pressure), in cases where there is excessive caecal contractility or fermentation then it is conceivable that you would get retrograde flow of faecal matter back into the terminal ileum. This would potentially cause small bowel bacterial overgrowth (SIBO) and I showed how in several patients with this type of motility pattern, subsequent lactulose hydrogen breath tests had been positive.

Interestingly, in addition to abnormal responses, just as importantly is the ability to exclude certain conditions. I showed an example of one patient that had been on laxatives for 10-years for suspected constipation, but the WMC showed that her transit was completely normal. This patient was started on a new therapy which stabilised immune cells prior to eating and had become asymptomatic almost immediately.
It is also possible to see the effect of extrinsic factors on gut motility with the WMC. Suppression of colonic activity was seen when asleep and this increased upon waking (normal colonic wake reflex) for example. In severe constipation patients, it has been reported that these reflexes can be absent. Finally, I showed examples of hyper and hypo contractility in the recto-sigmoid region in two patients with proven rectal hyper and hypo sensitivity. In summary, it is early days in terms of understanding what the WMC can contribute to the understanding of the pathophysiology of various GI conditions which manifest often as overlapping upper and lower GI symptoms.

What is certain is that the technique is much more patients friendly than small bowel manometry, does not expose patients to radiation as with scintigraphy / colonic marker studies and does not tie up departmental resources for many hours like most of the existing techniques. Whilst the cost of the capsule (around £420) is not inconsiderable, put in the context of these other issues, it becomes more cost effective. The meeting finished with an open floor discussion about the days events and the issues that they raised.

**Summary:** In summary, the 1st Neurogastroenterology training day had covered many of the issues that we face in tackling the broad range of patients with lower GI disorders. By putting these new technologies in the context of existing methods, it was clear to see some of the gaps that they may fill in our knowledge and help to better target therapeutic strategies in the future. From a training perspective, we want to provide access to educational material and training events easier for interested individuals and all of the presentations from the training event can be downloaded from a secure website using the instructions given below. We hope to host an upper GI event in the Autumn of this year and will be sending out details in the next couple of months. Many thanks to all those that attended and contributed to a successful day.

**Instructions for download:**
Go to – [https://www.aisecure.co.uk](https://www.aisecure.co.uk)
Username – diagnostics@alimentaryinnervations.co.uk
Password – neurogastro1
IQIPS: ACCREDITATION FOR DIAGNOSTIC PHYSIOLOGY SERVICES:

John de Caestecker  
President, AGIP  
Medical Advisor, IQIPS Governance Group

What is IQIPS?

IQIPS (‘Improving Quality in Physiological Diagnostic Services’) is a program of service accreditation initiated by the Chief Scientific Officer, Professor Sue Hill. The program is hosted by the Accreditation Department of the Royal College of Physicians of London (which already hosts a number of other service accreditation programs, such as Endoscopy, Occupational Health and Allergy Services). It covers all physiological diagnostic services, including audiology, vascular science, cardiac physiology, respiratory physiology, neurophysiology, urodynamics, ophthalmic science … and of course GI Physiology.

Why is this happening?

The principal aims are to recognise, promote and improve quality practice in physiological diagnostic (and interventional where relevant) services across all 8 physiology specialisms. This will raise the profile of physiological diagnostic services across organisations and with commissioners and patients. It will validate success as well as seeking to drive up quality, in a very similar fashion to what has been achieved by JAG Endoscopy accreditation over the last 6 years.

This will assure commissioners of the quality of services they may wish to commission, and has been chosen as the quality standard to be achieved for service providers wishing to compete under the new ‘Any Qualified Provider’ (AQP) scheme announced by the government. It is likely also to be used by patients in deciding where they want to have tests done, as the aim is to have details of accreditation status in the public domain.

What has happened so far?

Over the past 2 years, standards have been developed and agreed in consultation with physiological scientists and medical advisors for each discipline as part of an advisory group convened by the Chief Scientific Officer. The standards are grouped in 4 ‘domains’: Patient Experience, Facilities, Resources and Workforce, Safety and Clinical, see Figure 1.
Several standards underpin each domain (for example, Figure 2 for the Patient Experience domain). These have been derived and modified from previously existing standards developed for Radiology and Endoscopy accreditation. For 3 of the 4 domains, the standards are generic to all 8 physiology disciplines, with the Clinical Domain being more specific to each specialism.

**FIGURE 1**

![Diagram showing 4 key domains: Facilities, Resources and Workforce, Patient Experience, Safety, and Clinical, with standards and criteria levels](image)

**FIGURE 2**

<table>
<thead>
<tr>
<th>Standards</th>
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<tr>
<td><strong>PE1</strong> The service implements and monitors systems to ensure patients are able to access patient friendly information about what happens before, during and after specific examinations/procedures.</td>
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<tr>
<td><strong>PE2</strong> The service implements and monitors systems to ensure the privacy, dignity, comfort and security of patients are respected throughout contact with the service.</td>
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<td><strong>PE3</strong> The service implements and monitors systems to ensure informed patient consent is obtained for each procedure.</td>
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<td><strong>PE4</strong> The service implements and monitors systems to ensure that service delivery is patient focused.</td>
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<tr>
<td><strong>PE5</strong> The service implements and manages systems to ensure that patients are able to feedback on their experience of the service and that the feedback is acted upon.</td>
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Below each standard a set of criteria have been developed. This is illustrated in Figures 3 for one of the standards under the **PE** domain. The full list of standards is available at:

http://www.rcplondon.ac.uk/sites/default/files/iqips_standards_and_criteria_03-06-11.pdf

<table>
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<th>PE1 Criteria</th>
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<tr>
<td><strong>PE1 C1</strong></td>
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<tr>
<td>There are defined roles and responsibilities for each area of development and maintenance of patient information</td>
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<tr>
<td><strong>PE1 C2</strong></td>
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<tr>
<td>There are systems in place to ensure that patients are provided with information within specified timescales about the details and purpose of their examination/procedure to allow preparation for each appointment</td>
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<tr>
<td><strong>PE1 C3</strong></td>
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<tr>
<td>There are systems in place to ensure patients are able to access information in relevant formats</td>
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<tr>
<td><strong>PE1 C4</strong></td>
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<tr>
<td>There are systems in place to ensure patients are aware who is present at and who is performing their examination/procedure</td>
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<tr>
<td><strong>PE1 C5</strong></td>
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<tr>
<td>There are systems in place to ensure patients know how, when and by whom results/reports will be communicated</td>
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<tr>
<td><strong>PE1 C6</strong></td>
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<tr>
<td>There are systems in place to ensure that patients have access to information about peer/self-help and support groups</td>
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<tr>
<td><strong>PE1 C7</strong></td>
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<tr>
<td>There are systems in place to ensure patient information materials are developed and reviewed with lay/patient representatives and updated within specified timescales</td>
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**FIGURE 3**

The standards have been piloted by most physiology disciplines, including GI Physiology, with feedback from the piloted sites and peer assessors, including time concerns, difficulty in meeting standards, or impracticality of some criteria. Feedback has also been sought from stakeholder organisations (for instance, AGIP and the BSG), received and acted upon. There is a willingness to adapt and modify the process – for instance, some standards (such as safety standards relating to administered pharmaceutical agents or radio-isotopes) are not relevant to most GI Physiology practice and will thus not be applicable.

**What are the next steps?**

Registration of interest is encouraged at the Royal College of Physicians IQIPS website http://www.rcplondon.ac.uk/projects/iqips.

Accreditation is VOLUNTARY, as it is for Endoscopy services, but after 6 years virtually all endoscopy units have engaged in the process after a slow start.

Audiology will be the first discipline to engage in the process, since this is one of the diagnostic services identified for ‘AQP’ – and, as stated above, service accreditation will be an essential step to qualification to provide a service to NHS patients.

The process for GI Physiology is scheduled to start in September 2012. Following an expression of interest, units will (at a later date) be able to access the ‘Self Assessment and Improvement Tool’ (SAIT – see Figure 1 and Figure 4), which will be web- based. The proposed user interface is illustrated below, and is similar to that for the Endoscopy Global Rating Scale.
You will notice that on the right hand column of the SAIT page has levels – D is the minimum level, rising to C and B. There will be ‘A’ level criteria but these have not yet been developed – it has been decided what level B will be required for accreditation.

Once a unit decides that it meets the criteria for accreditation, it will be able to apply for assessment of the evidence (physical and/or electronic) supporting this, by trained peer assessors (i.e. physiological scientists from other units). This will be organised by the recently commissioned accreditation provider UKAS, which already runs the established Radiology accreditation program. UKAS will administer the process and will accredit units based on the formal assessment process.

The assessment process used by JAG for Endoscopy accreditation has been a positive and supportive experience, with assessors going out of their way to support units – for instance, by raising the profile of the visit by insisting on Trust Board level representation at the feedback for visits, and asking (and often facilitating) the clinical leaders of the assessed unit what they need help with. Many endoscopy units can attest that this has resulted in significant investment to improve the service to a good standard.

**Will there be a cost?**

It is recognised that there will need to be a differential cost so as not to disadvantage smaller units, and also some recognition of ‘economies of scale’ where a unit delivers 2 or 3 physiology diagnostic services, as there will be a lot of common ground between disciplines as far as the assessment process is concerned. For 2012 the subscription fee will start at £500 (excl. VAT) annually for one specialism to enrol for SAIT, rising to £2,100 (excl. VAT) which will be an annual accreditation fee once accreditation has been achieved. Multiple delivery locations and multiple specialisms will be required to pay more - the exact amount is to be confirmed at a later date.
This is in order to fund the cost of hosting the website for SAIT, the assessors and the administrative element of UKAS. For endoscopy a single much larger sum was required for the assessment visit, but it has been decided to ‘spread’ this for IQIPS. It is likely that there will be a 3 year accreditation cycle:

Year 0: Evidence uploaded and assessed (web based assessment) followed by an assessment visit by both an assessment manager and a peer assessor

Year 1: Will require electronic submission of ‘evidence’ and a web based assessment by the assessment manager

Year 2: Web based assessment followed by a site surveillance visit by the assessment manager

Year 3: Will require electronic submission of ‘evidence’ and a web based assessment by the assessment manager

This all sounds like hard work and may not be for me?

It is voluntary. It will take time and it is NOT envisaged that every unit will come up to ‘scratch’ in only a few months. For Endoscopy, most units took 2-3 years to achieve accreditation – some were much faster. Once processes have been put in place to meet the standards, these standards may be the same for several different disciplines within a department – or indeed among 2 or 3 departments in the same organisation. As for the Endoscopy Global Rating Scale, criteria will be underpinned with a growing ‘Knowledge Management System’ (KMS – see base of Figure 1). This will mean that you won’t have to re-invent the wheel, but will be able to use and adapt processes/guidance etc developed by other units.

Small units, especially those with a single physiology practitioner who may have a nursing rather than clinical science background, may find this very challenging – it does require time investment. The ‘carrot’ of accreditation is that is means achieving a standard of excellence of which a physiology department can rightly be proud.

It will mean thinking out of the box – many units may well not actively invite patient feedback in a formal way, or if they do, there may not be a process to allow a responsive service. It might mean smaller units considering ‘buddying’ with nearby larger units.

AGIP wishes to support GI Physiology members in relation to the IQIPS process and to hear of issues, difficulties – and to share your good practice with others.

Future Meetings

Forthcoming Events:

We hope to publicise forthcoming meetings and educational events. We would like to invite interested parties to contact the NewWave editor (warren.jackson@hey.nhs.uk) to have their details included in future issues.

March – Nov 2012 Medical Measurement Systems (MMS) has recently announced a new schedule of web seminars for 2012:
27th March 2012  Impedance-pH studies
4th April 2012  Paediatric Impedence-pH studies
24th April 2012  Anorectal manometry (HRAM) & Colonic manometry
31st May 2012  Paediatric High Resolution Manometry (HRM)
21st June 2012  High Resolution Manometry (HRM)
2nd Oct 2012  Impedance-pH studies
16th Oct 2012  Anorectal manometry (HRAM) & Colonic manometry
24th Oct 2012  Paediatric Impedence-pH studies
8th Nov 2012  High Resolution Manometry (HRM)
28th Nov 2012  Paediatric High Resolution Manometry (HRM)

Each session has a limited enrolment and is FREE of charge; see their website for further information:

25th April 2012  Guy's & St Thomas' Endoanal Ultrasound Course
For further details contact Deepa Solanki / Monica Lyons 0207 1889918 / 0207 188 9899

17th & 18th May 2012  Oxford Pelvic Floor Centre & Covidien Masterclass

19th – 22nd May 2012  Digestive Diseases Week (DDW)
San Diego Convention Centre, San Diego, California, USA
Website: www.ddw.org

17th – 20th June 2012  Digestive Diseases Foundation (DDF) -Replacing the BSG
Arena and Convention Centre (ACC), Liverpool
Website: www.ddf2012.org.uk

1st – 3rd July 2012  Association of Coloproctology of GB & Ireland 2012 Annual Meeting
The Convention Centre, Dublin, Ireland
Website: www.acpgbi.org.uk

October 2012  Synmed Ltd has recently announced a variety of training events taking place in October 2012:

2nd Oct 2012  High Resolution Anorectal Manometry (HRaM)
3rd Oct 2012  High Resolution Impedance Manometry (HRiM)
4th Oct 2012  Impedance/pH Reflux Testing (Advanced - Adults)
5th Oct 2012  Impedance/pH Reflux Testing (Advanced - Paediatrics)

For more information, please email Eleni.Kyriacou@synmed.co.uk

20th - 24th Oct 2012  United European Gastroenterology Week (UEGW)
Amsterdam RAI Convention Centre, Netherlands
Website: www.uegw12.uegf.org
Synmed Ltd., a leading U.K. specialist supplier of gastroenterology diagnostic/therapeutic equipment and exclusive U.K. distributor of Sandhill Scientific Inc., recently held an Impedance/pH Reflux Testing & High Resolution Impedance Manometry Seminar at The Grosvenor Hotel (Victoria, London) from 28th February – 1st March 2012, which was attended by 45 Clinicians from the U.K. and Europe. Due to the success of this event, further dates have been identified for the next training events (TBC):

If you would also like to benefit from the FREE 24 hour on-line Sandhill University (which includes training for oesophageal and anorectal manometry, as well as acid (pH) and impedance/pH reflux testing and a very systematic step-by-step approach from set-up through performing and analyzing the study) please click here to take a test run through two of the on-line programs.

To register your interest in training events taking place October 2012, or for more information, please email Eleni.Kyriacou@synmed.co.uk or contact us on 01992-782-570.

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We welcome any suggestions for improving this e-newsletter for future publications. We would also welcome from all our members any articles, interesting case studies, any relevant information obtained at recent conferences etc, which would count as a publication and contribute towards your CPD and KSF portfolios. Please contact (via email) the NewWave editor warren.jackson@hey.nhs.uk. We look forward to hearing from you.