pathology@viapath

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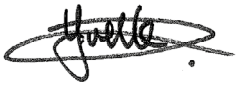
viapath
pioneers in pathology

Message from the editor

A momentous milestone was achieved when, on Thursday July 5th, the NHS celebrated its 70th birthday. The inauguration of the NHS soon transformed the health of the nation and quickly became the envy of the world. The NHS has enabled pathology to touch all of our lives, from before we're born to even after we die, and today 95% of clinical pathways rely on patients having access to timely and accurate pathology services.

Who would have thought, back in 1948, how the NHS would expand and develop across all of its services, including pathology? This edition of "pathology@viapath" serves to illustrate this. Some of the pioneering work being carried out is showcased, such as the advances in MRI scanning and the detection and monitoring of chronic kidney diseases as well as developing knowledge on involvement of vitamin K_1 in certain diseases. One of Viapath's Finance Business Partners explains what his role involves and highlights a new function recently introduced into pathology.

Significant occasions are also times for looking forward and it is heartening to read of two initiatives. The first is Healthcare Science Week which encourages and inspires school children to take up science and showcases some of the work they could do in the NHS. The other is Viapath's Career Development programme which assists those new to pathology in the development of the skills they require to become proficient scientists. Both of these lead me to think that the NHS will continue to flourish.



Primary care requesting patterns for estimated glomerular filtration rate and compliance with NICE chronic kidney disease guidelines

What is chronic kidney disease?

Chronic kidney disease (CKD) is defined as abnormalities of kidney structure or function lasting for at least 3 months, with adverse clinical consequences[1]. It is difficult to detect at early stages since the majority of patients are asymptomatic. A small but significant percentage of cases potentially progress to end-stage renal disease (ESRD) regardless of the underlying pathophysiological cause. CKD is a significant cause of mortality and morbidity, and escalating health costs related to cardiovascular disease and renal replacement therapies.

Diagnosis and monitoring of CKD is crucial in preventing or delaying development of ESRD, reducing occurrences of complications and, importantly, lessening the burden on the health care budget.

What are the tests for the diagnosis and monitoring of CKD?

Detection and monitoring can easily be achieved using simple tests such as an estimated glomerular filtration rate (eGFR) calculation in conjunction with serum creatinine and urine albumin creatinine ratio (ACR).

The serum and urine creatinine results, in our audit, were obtained using the Jaffé method (which is calibrated against isotope dilution mass spectrometry (the reference method)) as well as urine albumin using immunoturbidimetry. eGFR calculation, in our laboratory, is still based on the 4-variable Modification of Diet in Renal Disease (MDRD) equation.

NICE CKD classification & recommendations for follow up

In 2012[1], Kidney Disease: Improving Global Outcomes (KDIGO) guidance on the evaluation and management of CKD, stratified CKD according to eGFR (Grade 1 to Grade 5) and ACR (Grade 1 to Grade 3). According to this, decreased eGFR and increased ACR indicate increased risk of adverse outcomes in the disease process. Further to that, in 2015, NICE updated their guidance (CG182) on identification and investigation of individuals with CKD including frequency of monitoring of eGFR in each CKD category[2].

What did Viapath audit?

In our retrospective audit, we focused on adult requests from primary care to Viapath's Clinical Biochemistry laboratory, King's College Hospital, for eGFR and/or ACR for 2 months from January 2017. Frequency of monitoring of eGFR and ACR was determined over a one-year period for each patient and compared with NICE recommendations (Table 1).

CKD is a significant cause of mortality and morbidity, and escalating health costs related to cardiovascular disease and renal replacement therapies.

		ACR Categories (mg/mmol), description and range)		
		A1 <3 Normal to mildly increased	**A2 3-30** Moderately increased	**A3 >30** Severely increased
eGFR categories (ml/min/1.73m²), description and range	**G1 ≥90** Normal to high	**F ≤1** T- 24(20.5%) Y-9% N-12%	**F 1** T- 10(8.5%) Y- 4% N -4%	**F ≥1** None
	G2 60-89 Mild reduction related to normal range for a young adult	**F ≤1** T- 43(36.7%) Y-15% N-22%	**F 1** T- 8(6.8%) Y-3.4% N-3.4%	**F ≥1** T- 4(3.4%) Y-1.7% N-1.7%
	G3a 45-59 Mild –moderate reduction	**F 1** T- 7(6%) Y-1,7% N-4.3%	**F 1** T- 2(1.7%) Y- 0.9% N-0.9%	**F 2** None
	G3b 30-44 Moderate-severe reduction	**F ≤2** T- 3(2.6%) Y-0 N-2.6%	**F 2** T- 1(0.9%) Y-0 N-0.9%	**F ≥2** None
	G4 15-29 Severe reduction	**F 2** None	**F 2** None	**F 3** T- 1(0.9%) Y-0 N-0.9%
	G5 <15 Kidney failure	**F 4** None	**F ≥4** None	**F ≥4** None

Table 1. Frequency of monitoring of eGFR (Recommended (F)= number of times per year by eGFR and ACR category) F=Frequency of tests recommended in NICE guidance, T=total cases, Y=overall compliance with NICE guidelines N=overall non-compliance.

Compliance of primary care for NICE recommendations

A total of 117 patients (55 males), aged 58 (±14) [mean (±SD)] years were categorised according to CKD grades as in table 1. The majority of patients, 43 (36.7%), were found in the G2A1 CKD category with mild reduction of eGFR and normal to mildly increased ACR.

The second common category for monitoring in Primary Care was A1G1 (24 cases: 20.5%). Interestingly, none of the patients from our cohort belonged to either the G1A3, G3aA3, G3bA3, G4A1, G4A2 or the eGFR kidney failure categories. Only ACR was requested in 14 (12%) cases within one year.

The overall compliance of monitoring CKD with NICE guidance in this study group was seen only in 42 (36%) cases whilst 75 (64%) cases were non-compliant.

Compliance of monitoring of CKD with NICE recommendations in each category as a percentage to the total number of patients was demonstrated in both table 1 and figure 2.

Conclusions

In summary, it was found that CKD monitoring was not adequately performed in line with NICE recommendations. Over requesting occured at lower CKD grades (Grade 1-2) and under requesting occured at higher CKD grades (Grades 3-4). There is some evidence found in literature that eGFR graphs help to identify patients with deteriorating renal function earlier[3]. Early diagnosis of CKD has been advanced notably since nationwide introduction of eGFR reporting in the primary care Quality and Outcomes Framework as well as increased public and health care professional awareness of CKD. Nevertheless, despite all these measures, overall 19% of cases were still identified as late presentations according to the Renal Registry report issued by Renal Association, UK in 2013.

The laboratory can become the key link in engaging primary care and renal physicians to develop effective local policies for monitoring CKD.

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1.National Kidney Foundation. KDIGO 2012 Clinical practice guideline for the evaluation and management of chronic kidney disease. Kidney Int Suppl 2013;3:1-50.

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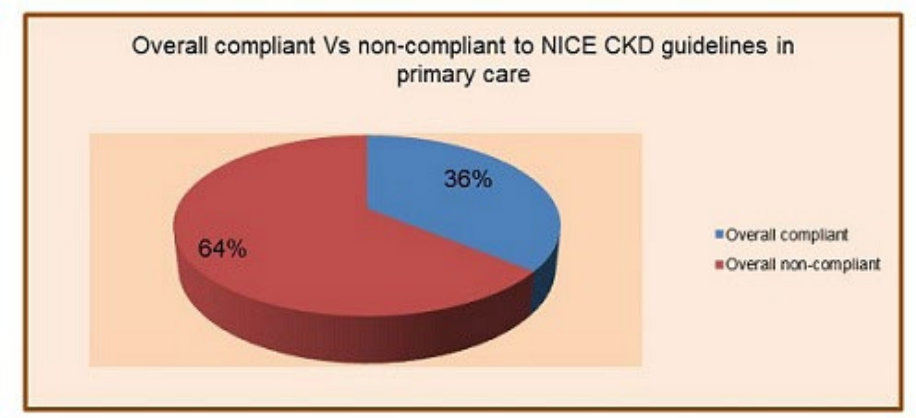

Figure 1- Overall compliant Vs non-compliant to NICE CKD recommendations in primary care

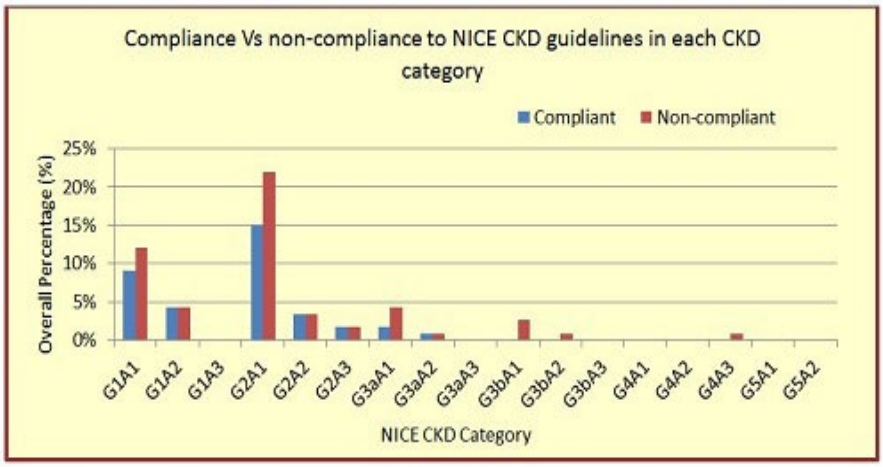

Figure 2- Compliance to NICE CKD guidelines of monitoring CKD in each category

Potential toxicity from use of gadolinium based contrast media

What is gadolinium (Gd)?

Gd-based contrast agents (GBCAs) have been widely used as magnetic resonance imaging (MRI) contrast media since the late 1980's. The paramagnetic properties of the GBCA's enhance signal intensity through the shortening of the time taken to temporarily magnetise nuclei (within tissue) in the direction of magnetic field and consequently improve the visibility of internal organs, blood vessels and tissues.

To date, nine GBCA's have been used globally for clinical use (see table below) and are classified into two groups, based on structure of the ligand binding. In the 'macrocyclic' group, the Gd^{3+} ion is caged within a pre-organised cavity of the ligand, whereas in the 'linear' group, the ligand has linear geometry (open chain). Each category can in turn be subdivided into ionic (dissociates/dissolves as charged particles in solution) or non-ionic, based on charge. The macrocyclic molecule is less likely to release the Gd^{3+} ion (which is toxic in the 'free' form) and is thus more stable than the linear form, whilst the ionic linear chelates are more stable than the linear non-ionic chelates.

The link between GBCA's and nephrogenic systemic fibrosis

Until about a decade ago, the GBCA's were believed to be rapidly excreted in intact form, and thus considered safe to use at recommended doses in subjects with normal renal function. However, an association between the administration of GBCA (and linear contrast agents in particular) and the development of a rare, but severe condition Nephrogenic Systemic Fibrosis (NSF) was described in 2006 in patients with renal insufficiency[1]. NSF is associated with widespread progressive tissue fibrosis arising from the deposition of fibroblasts and collagen: the aetiology is believed to be the release of gadolinium ions from the chelated complex(es) due to impaired clearance. Limiting the use of GBCAs in patients with renal failure and encouraging the use of more stable GBCA's (and at low doses), has resulted in a marked fall in NSF cases.

More recent reports have however, emerged indicating that gadolinium may be retained in various tissues of the human body (including brain, kidneys and bone) even in patients with normal renal function, leading to neurological, musculoskeletal and dermal consequences[2]. Retention is higher in patients receiving multiple MRI scans. Studies in animals have similarly demonstrated increased tissue deposition of Gd following exposure to GBCA's. There is currently no consensus regarding the clinical significance of accumulation (and potential mechanism for toxicity) and treatment of gadolinium accumulation. Thus the FDA has asked manufacturers of these GBCA's to conduct human/animal studies to assess their safety.

Case Study:

Gd concentrations were measured in urine samples obtained from a 50 year old male patient who had had exposure to Gadovist contrast medium (macrocyclic, non-ionic) MRI, every 4-6 months since August 2011 and every quarter for the last two years, for a brain glioma. The renal function in the subject was normal during this period. Gd concentrations were measured in samples obtained pre-, during and post chelation with the chelating agent succimer (Dimercaptosuccinic acid, DMSA), that is commonly used in the treatment of lead, mercury and arsenic poisoning.

Product name	Agent type
Dotarem - gadoteric acid	Macrocyclic ionic
Gadovist - gadobutrol	Macrocyclic non-ionic
Prohance - gadoteridol	Macrocyclic non-ionic
Magnevist - gadopentetate dimeglumine	Linear ionic
Multihance - gadobenate dimeglumine	Linear ionic
Omniscan - gadodiamide	Linear non-ionic
Optimark - gadoversetamide	Linear non-ionic
Primovist - disodium gadoxetate	Linear ionic
Vasovist – trisodium gadofosveset	Linear ionic

Gd was measured in Viapath's Trace Element laboratory using Inductively Coupled Plasma Mass-Spectrometry in standard mode and using rhodium as the internal standard. Concentrations were corrected for creatinine.

Gd excretion was significantly elevated (~75-fold) in samples collected during chelation therapy with DMSA. Increased excretion was still evident 2 days after chelation therapy had been halted. Excretion seemed to normalise 9-10 days after chelation therapy. These measurements provide evidence of gadolinium build up following MRI scans. However it is unclear if the Gd accumulation is in the free form (Gd^{3+}) or in association with ligand(s). It is feasible that the accumulation could contribute to clinical complications.

For further information, please contact

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References:

1. Marckmann P. Nephrogenic systemic fibrosis: suspected causative role of gadodiamide used for contrast-enhanced magnetic resonance imaging. J Am Soc Nephrol. 2006. 17; 2359-62

2. Ramalho J et al. Gadolinium-Based Contrast Agent Accumulation and Toxicity: an update. Am J Neuroradiol. 2016, 37; 1192-98

Reach out for Healthcare Science Week

Krutika Deuchande, Biomedical Scientist at Viapath's Haemostasis and Thrombosis Laboratory, writes about the recent Reach Out for Healthcare Science week.

What is Reach Out for Healthcare Science?

Healthcare scientists are vital to the functioning of the NHS. Even though they only make up 5% of the total NHS workforce, they are involved in over 80% of patient diagnosis. As students approach their GCSE's they have to think about their career options, making this the perfect time to present them with the various healthcare science career opportunities.

The Reach Out for Healthcare Science programme is now in its sixth year with 300 students and over 80 healthcare scientists involved. The week-long Kings Health Partnership (KHP) event provides students who enjoy studying science at school access to healthcare science work experience and aims to increase students' and their families' awareness of the range of career opportunities in healthcare science.

Students get to experience life in busy London hospitals and universities, meet healthcare scientists, take part in a wide range of practical activities using real equipment and find out what is required to follow a career in healthcare science.

Figure 1 - Students using dipstick urinalysis to diagnose patients with diabetes and urinary tract infection.

Reach Out for Healthcare Science 2018

This year's event was organised by Viapath's Future Leaders in Innovation, in collaboration with Exscitec, the STEM outreach provider, and Richard Fernandez Principal Physicist at the Department of Nuclear Medicine at Guy's and St Thomas'. The week commenced with a talk on "What is Healthcare Science?" given by Louise James a Senior Biomedical Scientist at St Thomas Hospital, followed by an inspirational life journey talk by the Deputy Chief Scientific Officer of NHS England, Fiona Carragher and finally a talk on genomics from Vivienne Parry, Science writer and broadcaster.

The second half of the day involved leading the students through a case study about diagnosing a patient with severe acute respiratory syndrome (SARS), to showcase how each of the various healthcare science disciplines can be involved in diagnosing a single patient.

Subsequent days involved various practical activities in each of the healthcare science disciplines (Life Sciences, Physiological Sciences, Medical Physics & Clinical Engineering and Bioinformatics). These included creating ear mould impression on dummy ears, extracting DNA from their own saliva, urine analysis on patients with diabetes, capturing retinal photographs, making a cyclotron out of a ping pong ball and tin foil, and performing percutaneous coronary intervention.

The week culminated in a poster session where the students presented what they learned during the week to each other, their teachers and parents. The energy and enthusiasm in the subsequent awards ceremony (with prizes kindly donated by the Wellcome trust) was a joy to behold.

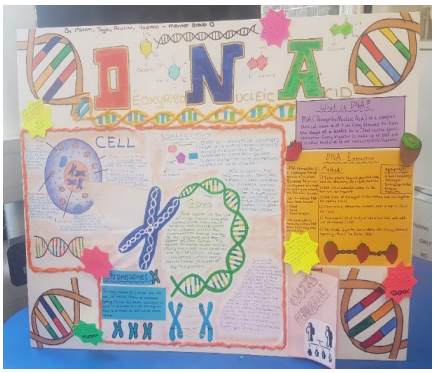

Figure 2 - Best poster design winner.

Figure 3 - Students extracting DNA strands from Kiwi and strawberries

All the students highly valued meeting real healthcare scientists and finding out about the many and varied careers and career pathways. Over half initially thought that medicine and nursing were the only science related careers in hospitals and, before this week, couldn't name any healthcare science jobs. At the close of the week when students were asked what they'd consider a career in, comments included "I want to be a clinical scientist in Nuclear Physics" and "I would like to work in Haematology where they get to diagnose malaria".

If you are interested in getting involved with the 2019 event please contact

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The effects of vitamin K_1 administration in Pseudoxanthoma elasticum patients. A pilot study

Why was Pseudoxanthoma elasticum studied?

Pseudoxanthoma elasticum (PXE) is a rare disease caused by mutations in the ABCC6 gene encoding multidrug resistance-associated protein 6 (MRP6). The disease is characterised by progressive calcification and loss of function of elastic fibres causing central blindness, skin papules, and vascular calcification. Several hypotheses have been postulated and, due to its involvement in regulation of vascular calcification, it has been suggested that vitamin K may be involved. However the disease pathogenesis is not yet completely understood. In this study, patients affected by PXE were compared to PXE carriers and non-carriers. The aim was to look at baseline levels of vitamin K-dependent proteins and vitamin K metabolites and to determine whether parenteral administration of phytomenadione (vitamin K_1) was effective in altering their circulatory concentrations.

Methodology used

Patients and healthy controls were compared:

- Eight PXE patients with typical clinical symptoms (skin, retinal, and vascular calcification) and two with ABCC6 causative mutations
- Thirteen clinically unaffected first-degree patients' relatives (9 carrying one ABCC6 mutation and 4 non-carriers).

For this study serum vitamin K, urinary vitamin K metabolites and vitamin K dependent proteins (serum carboxylated and undercarboxylated osteocalcin, Gas6 and undercarboxylated prothrombin (PIVKA-II)) were assessed at baseline and after 1 and 6 weeks post treatment with vitamin K_1 (10 mg IM).

Summary of the results

The comparison of PXE patients, heterozygotes and non-carriers revealed differences in baseline concentrations of serum vitamin K_2 (MK-4) and of urinary vitamin K metabolites. The response of circulating vitamin K-dependent proteins to vitamin K_1 administration was similar in all groups.

Conclusion

The study showed that the physiological axis between vitamin K_1 and vitamin K-dependent proteins is preserved. However, differences in the concentrations of vitamin K metabolites and of MK-4 suggest that vitamin K metabolism could be altered in PXE patients. Further studies are required to establish to what extent vitamin K metabolism is altered and the cause of this biochemical anomaly.

The full report can be found at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5911498/pdf/fmed-05-00086.pdf

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Viapath's Career Development Programme (VCDP)

In 2017, Viapath's Future Leaders in Innovation created the Viapath Career Development Programme (VCDP). The VCDP is a 2 day training course filled with a range of informative and interactive lectures that are directed to Viapath's junior staff members, particularly those who want to achieve career progression within healthcare science. Essentially, the main aim of the programme was that the delegates should gain important skills and knowledge about working in a diagnostic laboratory and use this to their advantage in their career journeys. This year's VCDP took place on 11th and 12th May 2018.

An inspirational start

The VCDP was opened by Viapath's Divisional Operations Director for Reference Services, Analie Booth, who gave an inspiring talk about her career journey, from where she started through to how she progressed to her current role within Viapath.

An introduction to Viapath's range of laboratory disciplines

Due to the vast range of laboratories within Viapath, it can often be quite difficult for junior staff to decide on which discipline to specialise their training in. To help them, a number of short lectures gave a snapshot into the different laboratory disciplines that are available at Viapath. The sections covered were Microbiology, Blood Sciences, Genetics, Immunology, Haemostasis and Bioinformatics.

The importance of excellent training

Viapath's Scientific Portfolio Training Officer, Andrea Wilson, presented an insightful session on collecting portfolio-based evidence. As the completion of a training portfolio is an essential step for a career in healthcare science, this session focused on the importance of receiving good training. To demonstrate this, the delegates were given the task of making origami flowers: firstly using a vague set of instructions, then with more detailed visual aids including diagrams and a video.

Scientific calculations and quality

The delegates were also given the opportunity to improve their scientific calculation skills in an informative tutorial presented by Biomedical Scientist, Payalben Patel. This was followed by an interactive session on the topic of "Quality in the Laboratory", given by Biomedical Scientist, Samantha Sheppard, which included the delegates having to suggest some quality improvements for Viapath.

Presentation skills

Karon Campbell, Viapath's Learning and Development Manager, led a training session on presentation skills which covered the skills and qualities of a good presenter as well as how peoples' different learning styles can direct how a presentation should be delivered.

Haematological malignancy case study

Viapath's Head of Cytogenetics, Robert Dunn, presented a case study on a patient with a haematological malignancy, explaining the patient's sample journey through the Haematological Malignancy Diagnostic Centre. Then the delegates took part in a karyotyping exercise where they had the task of pairing and ordering chromosomes to form a complete set.

CV and interview skills

Nick Parkin, Clinical Scientist in Molecular Genetics, gave the delegates some useful tips on how to improve their personal statement writing skills and how to shine in interviews, focusing on the requirements for healthcare science laboratory-based roles.

VCDP close with some words of motivation

The VCDP was closed by Viapath's Chief Scientific Officer, Dominic Harrington, with some motivational words. He encouraged the delegates to become involved with things that they are passionate about, to seize the opportunities they are offered and to stay true to themselves.

Figure 1 - This year's group of VCDP delegates

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Links:

Listen to pathology podcasts from the Future Leaders in Innovation at http://www.viapath.co.uk/news-and-press/pathology-podcasts-from-viapath's-future-leaders-in-innovation-group

A day in the life of a Finance Business Partner

Chartered Accountants are often stereotyped as boring, tax-expert introverts who sit behind calculators all day crunching away at numbers. However, these stereotypes do not reflect the reality of what it's like to be a Finance Business Partner (FBP) at Viapath.

Fundamentally my role as an FBP can be summarised as "Support" and "Challenge"; I support the labs to achieve their operational goals and to understand their financial performance, and I challenge them to operate in a way that leads Viapath to achieve its overall organisational goals. In other words, I focus on adding value and I achieve this by working closely with other business areas, advising and supporting their strategic and operational decision-making through shared insights that drive improved business performance.

Of course, no day is ever quite the same. One minute I can be chasing up an important delivery or a payment to make sure the lab can continue to run smoothly, and the next minute strategising on joint efficiency savings with our Partners. But here's a flavour of a typical day in the Viapath Finance Business Partnering Team:

8am – Cycle, catch-up & coffee: Cycle into the office, catch-up with my immediate colleagues to understand their priorities and, of course a double espresso is a must to start each day.

8:30am – New test costing exercise: In response to customer demand, our Clinical Scientists have developed an improved rapid testing methodology which I need to understand in order to cost and price effectively. I'll need to recommend the price we should charge to make sure we cover all of the costs we'll incur in running the test (people, consumables, controls, quality, etc.) as well as offering the best price possible to our customers. It's common for there to be uncertainty over demand for a new test and, amongst other things, the number of tests in a batch can significantly affect the cost, so it's one of my most interesting challenges. Our operational teams are continuously innovating, and it is rewarding to assist them in expanding their test repertoire to meet our clients' and patient's needs, whilst also ensuring the strong financial growth that supports, for example, investment in new laboratory equipment.

9:30am - Finalise training slides for an upcoming "Finance for Non-Finance Managers" workshop: The Finance team contributes to the in-house Viapath Way and Management training programs by delivering a finance course for non-finance managers. As a finance professional, my technical skills and experience are important, but as an FBP, what's key is my ability to translate complex financial issues to my non-finance colleagues. What's equally important is then how I assimilate the business knowledge I learn every day in the labs, from my scientific colleagues, back into the numbers. It's a virtuous cycle of collaborative working that builds trust and supports stronger working relationships between me and my colleagues, and enables us all to succeed together.

10:30am – Half year forecast review meeting: We regularly review our financial performance against targets that we set. Whilst it's key to understand what has already happened, FBP's are always looking forwards too. Through our financial analysis we can facilitate change to ensure key operational, commercial and financial targets are delivered. As a result, this enables Senior Management to confidently make important decisions that impact and grow our business based on robust and accurate information.

12pm – Travel from Viapath's central HQ to King's College Hospital (KCH) where one of our five hospital-based sites are situated. As an adopted South Londoner myself, this also provides an opportunity to sample some of the best local West Indian food I've experienced since moving to London

1pm – Core customer meeting: I'm also responsible for managing the financial aspects of the relationship with KCH, my core customer. I regularly meet my counterparts there to discuss our commercial arrangements, resolve outstanding billing issues, ad hoc requests and generally discuss items of mutual benefit.

3pm – Service line review: As part of the day-to-day operations, I meet with my Service Delivery Managers frequently during the month, but there are one or two formal meetings like this that are always in the diary. In this meeting we review the operational and financial performance of the lab; we discuss what's happening, examine key performance indicators (KPIs) and their implications for the operation and finances, before planning how to resolve issues, cover potential risks or take advantage of opportunities.

5pm – Finalise Business Case for investment in new lab-based equipment: Linked to the development of new tests, our labs require investment in new technology which necessitates a full and robust financial appraisal. Whilst new business presents opportunities, it's important that we assess the feasibility of every case and its associated risks whilst also facilitating collaboration across the various subject matter experts throughout our business (e.g. Clinical & Scientific, Procurement, IT and Business Change) who contribute towards making a compelling business proposition to our internal decision-makers.

Genetics Laboratories awarded UKAS flexible scope

We are pleased to announce that Viapath's Genetics Laboratories have been granted a UKAS flexible scope for whole exome sequencing (WES) and preimplantation genetic diagnosis (PGD) testing. This will enable the laboratories to respond rapidly to new clinical requests and changes directed by NHS England for provision of genomics tests.

Flexible scope is granted when a laboratory successfully demonstrates a management system of sufficient quality to 'self-validate'. This achievement allows Viapath to add further targets to the existing WES and PGD tests without having to apply to UKAS to for an extension to our scope.

Viapath is the first medical laboratory in the country that UKAS has been accredited to ISO 15189:2012 which includes a flexible scope for part of the whole accredited scope.

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Viapath Nutris launches new tests

Viapath Nutris, our pathology-to-patient service, is pleased to announce the availability of four new test panels. Readers who place an order before October 31st 2018 can take advantage of a special introductory 10% discount by entering 3PCN10 at checkout.

For further information, please visit www.nutris.viapath.co.uk

D Express	My D+	Nutris VitaSorb	Nutris AquaSorb
Vitamin D	Vitamin D_2	Vitamin A	Thiamine (B_1)
-	Vitamin D_3	Vitamin D	Riboflavin (B_2)
-	-	Vitamin E	Vitamin B_6
-	-	Vitamin K	Folate (B_9)
-	-	-	Active B_{12}
-	-	-	Total B_{12}
-	-	-	Methylmalonic Acid (MMA)
-	-	-	Homocysteine
-	-	-	Fedosov Factor

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