

the **JOURNAL**
of the Faculty of Pharmaceutical Medicine



Digital Health

Journal of the Faculty of Pharmaceutical Medicine

Edition 4
Summer 2019

Digital Health

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WELCOME

PROFESSOR TIM HIGENBOTTAM
PRESIDENT
FPM



Welcome to the fourth edition of the Journal of the Faculty of Pharmaceutical Medicine. This edition offers an exciting range of articles focused on technology and communication. There are also some wonderful insights from Sharon McCullough into the journeys we make in entering our specialty of Pharmaceutical Medicine and a poignant book review by Alice Kay. An account of a Westminster Health Forum meeting on pricing and access to medicines at which Stuart Dollow was a key speaker is also given.

There have been a lot of developments here at the FPM offices over the last six months. The FPM welcomes our new Chief Executive, Dr Marcia Philbin, from the Royal College of Paediatrics and Child Health, who begins in

June (see page 10). Also, we have a new Head of Revalidation Operations Tony Roche starting soon, who joins us from the Royal College of Psychiatrists, and a new Revalidation Support Coordinator, Ben Fritchley.

Much has been achieved with our new strategy following the October 2018 review. Following the FPM Board meeting on the 16th May the plans have developed, and next steps agreed. An update can be found on page 10.

Do feed back your views and ideas, as this platform is to promote discussion. Best wishes for the next 6 months of the year.

Meet the speakers

FPM Education Day 2019 | 12 June 2019 | NCVO

**Ms Trishna Bharadia, Dr Lode Dewulf, Prof Theo Raynor,
Mr Mitch Silva, Mr Alastair Duns, Dr Asad Khan,
Dr Guy Yeoman, Dr Liz Clark**



ENABLING THE DIGITAL HEALTH INNOVATORS

"Yup, you're in AFib. This thing may have just saved your life." a doctor stated, referring to the Apple Watch that detected atrial fibrillation (AFib) in an otherwise healthy and asymptomatic 46-year-old individual. This story, which became popular in late 2018, is one of the numerous examples that demonstrate the transformative potential of digital technologies in patients' health.¹

Recognising the high potential of digital innovations in healthcare, the NHS launched the NHS Long Term Plan in January 2019, a 10-year plan, which welcomes digitally-enabled care.² In particular, this plan outlines ten top-priority steps to drive digital transformation, including the use of artificial intelligence (AI) and tools to capture patient data in order to empower clinicians to apply best practice.² Another step is WiFi installation across the NHS and use of applications (apps) to enable online consultations, monitoring of health records and instant appointment booking.²

Once a plan has been decided, thorough support is always crucial in order to bring it to life. Often innovations are generated in the academic or entrepreneurial environment and many of them face challenges being translated into clinical practice. A common bottleneck is the high level of specialisation that has disconnected the innovators from the clinicians. Also, there is a significant lack of resources and expertise.³ However, the landscape in the UK is changing. Several support programs, called accelerators or incubators, are available to meet a variety of needs and create a collaborative ecosystem with the ultimate goal being to enable the digital health innovators to improve patient care.

The NHS itself announced earlier this year the creation of NHSX, a new joint organisation to take forward the digital transformation in the NHS.⁴ The NHSX has a strong focus on resourcing the right technologies to meet NHS needs, and on training staff to build digital awareness. As Matt Hancock, Secretary of State for Health and Social Care, said: "Modern technology has an incredible potential to change people's lives for the better and revolutionise the care they receive." In addition, the NHS Digital Academy works in partnership with leading

universities to provide a year of training to generate future digital leaders; whilst the clinical entrepreneur training programme is offering clinicians training in entrepreneurship, through mentorship, coaching and sponsored attendance at networking events.^{5,6}

The DigitalHealth.London Accelerator, which supported the launch of medCrowd, the instant messenger for healthcare, enables the adoption of digital technology in London's NHS. The accelerator works with start-ups and small to medium-sized enterprises (SMEs) on projects that aim to relieve the high pressure on services and empower patients to manage their own health.

Among the services provided are:⁷

- Engagement with clinicians and healthcare experts
- Product refinement to meet NHS needs
- Business model development
- Market access and navigation

This program, run by the Health Innovation Network in London, had impressively already doubled the speed of progress of the companies involved by 2017!⁸



DR ASIMINA PANTAZI
SCIENTIFIC ADVISOR, MEDDIGITAL



DR FELIX JACKSON
FOUNDER AND MEDICAL DIRECTOR OF MEDDIGITAL



The Health Innovation Network is one of the 15 Academic Health Science Networks (AHSNs) across England, the only bodies connecting the NHS to academic organisations, local authorities, the third sector and industry, thus aiming to catalyse changes across the healthcare system.⁹

One of the most recent initiatives launched last October, the Diabetes Hothouse, brings together the forces of NHS England, the Association of the British Pharmaceutical Industry (ABPI) and the AHSNs to connect digital health innovators with pharmaceutical companies to develop digital innovations for diabetic patients.¹⁰ These technologies are aligned with the existing national diabetes priorities, including:

- Improving hospital safety
- Reducing amputation rates
- Improving treatment targets for early intervention
- Maternal health
- Mental health

The Health Foundry, strategically located opposite St Thomas' Hospital in London, provides not only mentorship support but also a collaborative workplace and a large network to bring together digital health innovators and key enablers.¹¹

Its neighbouring Simulation for Digital Health (SimDH) program is supporting health tech companies by offering free state-of-the-art facilities and peer support to its members, by combining the academic knowledge of the London South Bank University (LSBU) with the real-world experience of the private sector.¹²

The Digital Catapult is another catalyst in the UK that has a broad focus on future networks, AI and immersive technologies.¹³ However, this program also offers the potential to support artificial and virtual reality (AR/VR) projects to advance the way medical education and surgical training work.

MedCity, a world leading hub for life sciences research and commercialisation in the Greater South East of England, is dedicated to promoting life sciences investment and entrepreneurship, including digital

innovations.¹⁴

With the growing supportive landscape in London, innovative digital technologies are reaching patients much sooner than before. Apps, wearables, monitors, Artificial Intelligence (AI) and Virtual Reality (VR) systems are bringing important improvements in care. A key feature of all these programmes is enabling conversations and connecting experts towards a common goal: to eliminate the barriers imposed by distance, or the disconnect caused by specialisation.

A collaborative ecosystem has been formed that drives a digital culture with the potential to revolutionise healthcare. Given the current situation, we hope that the NHS Long Term Plan is not far from becoming a reality, and that introducing the right digital technologies where they are needed will improve care in future.

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THE CONTINUED EVOLUTION OF EVIDENCE-BASED MEDICINE IN A DIGITAL WORLD

Over the last decade, smartphone and wearable technology, facilitated by the internet of things, has created the environment for the greatest experiment in our history; and the potential to dwarf the current published scientific evidence base in the personalised treatment of patients (Fig 1). The continued explosion of data sources with increasing volume, variability and complexity, means that there are even greater insights to be gleaned from the wealth of data available. The result is a truly exciting time for interdisciplinary collaboration between software engineers, scientists, data scientists, health economists and medical professionals.

healthcare providers. Estimates suggest that clinicians miss approximately half of their patients' symptoms during treatment¹. This leads us to question why we are not currently using the personalised and electronic case-report forms in our pockets, i.e. our mobile phones, to take control of our personal health data.

Are we asking the right questions of the right people at the right time?

Understanding the patient perspective is integral to delivering high-value patient-centred care. Multiple studies have demonstrated that systematic monitoring

of symptoms using patient reported outcomes (PROs) can improve patient-clinician communication, clinician awareness of symptoms, symptom management, patient satisfaction, quality of life, and overall survival². PROs have the potential to systematically incorporate patient input, which is crucial for individual decision making. The most basic principle of the PRO is to highlight the impact of disease or infirmity on the day-to-day life of those affected, encapsulating all facets of importance to quality-of-life, and how these are influenced by the presence or elimination of

symptoms. However, it is important to appreciate that diseases are dynamic and complex, varying in time and between people, as factors such as new treatments, new side-effect profiles, and new technologies in other aspects of life change the overall impact of disease. The result is that a disease and PRO as characterised 10 years ago, is unlikely to be as valid today as it was then. For back pain alone there were 75 PROs cited in published literature between 2001 and 2010³, each slightly different and encapsulating different facets of quality-of-life, and each used to different degrees over this period, demonstrating how even within a single therapeutic area, perceptions regarding what matters can differ significantly.



Fig 1: The entire dataset of pubmed with every co-authorship networked across therapeutic areas and continents.

To date we have aspired to the concepts of personalised and precision medicines, targeting the genomic makeup of a single patient with a single condition. However, people and diseases are much more complicated than this, and the factors confounding disease status are several, making the true understanding of day-to-day symptomatology imperfect. With limited time available for consultation, combined with unpredictable disease fluctuations and the low likelihood that patients have accurately remembered how they have felt recently, or even over the past few months, this may be no surprise. However, this lack of information regarding the true burden of illness results in a lack of understanding by



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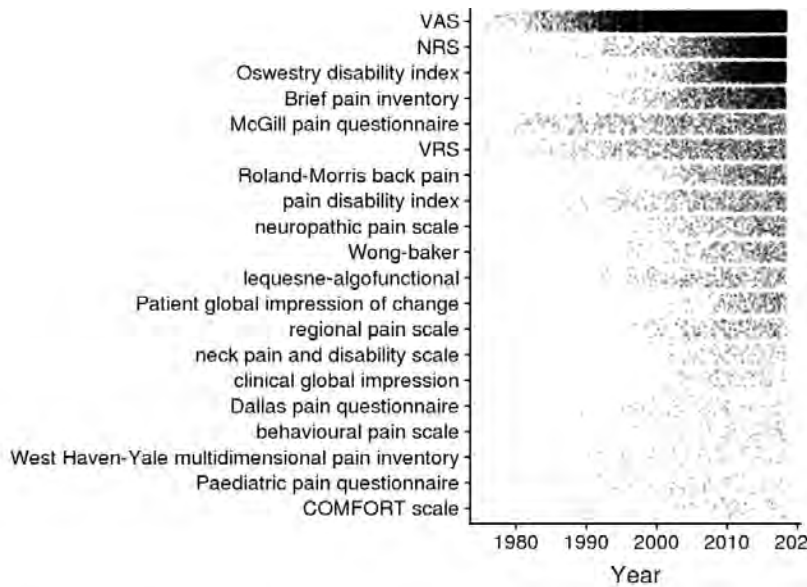


Fig 2: The evolution of the twenty most used Patient reported outcome Measures (PROMs) for lower back pain over time

The hierarchy of evidence is viewed differently by each stakeholder: Payer, Policy Maker, Regulator, HTA body and Physician. It is also no stretch to assume that the individual case study (or case-report), which nestles only slightly above expert opinion in the evidence pyramid, is currently one of the least favoured methods to demonstrate the value of an intervention. However, when such case studies number hundreds of thousands, which may be derived from Real World Data (RWD), using the power of the smart devices almost everybody uses, they may no longer merely prop up the evidence pyramid, but instead have the opportunity to sit on top of it, as a novel form of patient-centric real-world evidence. By harnessing the power of smartphone technology, and using this to our advantage, it is possible to transform the role of pharmaceutical evidence generation, enabling us to move beyond the randomised controlled trial (RCT) and Real-World Evidence (RWE) studies of today, to a position where we can describe the true longitudinal impact of therapeutic interventions at the individual level; while taking into account the myriad confounding factors, and clinical, socioeconomic and demographic heterogeneity that characterise routine clinical practice.

It has long been recognised that we are all different, let's embrace it!

'Give different ones [therapeutic drinks] to different patients, for the sweet ones do not benefit everyone, nor do the astringent ones, nor are all patients able to drink the same things' Hippocrates

Research which embodies PROs has historically focused on the archetypal cohort, those aged 18-65 with no co-morbidities or complicating features. However, it is patients outside this age range in whom we are often most interested, those likely to accrue the highest resource use, those with a more severe clinical outlook, and those in whom the benefit of treatment is likely to be the greatest; yet it is these patients for whom we have collected the least information. It is estimated that two-thirds of cancer patients are over 65 years, yet only 25% of cancer trial enrollees are of this age⁴. Similarly, Gurwitz and colleagues conducted a systematic review of clinical studies of drug therapies for treatment of acute myocardial infarction (MI), published between 1960 and 1991. Of the 214 trials (involving 150,920 study subjects) they analysed, 60% excluded persons older than 75 years of age, despite this group experiencing the greatest rates of mortality and morbidity from MI⁵.

Applying a population-based tool, based on observations collected in idealistic cohorts of those aged 18-65 and lacking comorbidities, may not be practicing evidence-based care. An intervention which improves mobility may have a greater impact on quality-of-life for an individual with no support network and no car, than for someone who is married with a family, and their own transport. Similarly, an intervention of which the side-effects include drowsiness, can be expected to have a greater impact on those who operate heavy machinery versus those who do not. As developing technology continues to increase our capacity to measure and analyse large amounts of data, it is possible to reduce this gap between what we think we know about the few (internally valid), and what we are yet to discover about the many (externally valid). By using the tools in most of our pockets, wider collection of PROs in diverse populations can ensure that the right questions are asked of the right people, at the right time, generating tens of thousands of n=1 trials; and with this, providing generalisable real-world estimates of disease and treatment burden which account for the myriad complicating factors often missing from published research.

What will this mean in the future and how can real time RWE change things for the better?

The advent of PROs has provided an opportunity to transform the way we monitor and record changes in symptom burden, and in doing so, has provided a benchmark for gauging value and satisfaction with care; yet the use of PROs in routine clinical practice remains low⁶. In order to make the most of the opportunities technology provides in terms of PRO measurement we may have to evolve our ideas of evidence generation, design evidence driven measurement pathways, utilise analytic capabilities, such as machine learning and block chain for example, and combine this with deep healthcare domain expertise. With ever changing disease spectrums, people living longer, multiple co-morbidities and drug side-effects, each impacting PROs in their own way, the result is that PROs have never had more potential to improve health care and patient experience.

Making the treatment and measurement of disease truly patient-centric is the next great opportunity in value demonstration. With the widespread use of smartphones, and the public being more engaged with managing their own wellbeing than ever before, the scale of the opportunity to collect and act on real-world data, which matters to real people, in situations that go beyond the restrictions of RCTs, is huge. We can create better and more informative contact with healthcare providers, inform evidence-based decision making based on the individual and not the cohort, and begin to place a value on the things that really matter to people in the real world.

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WHEN BREATH BECOMES AIR BY PAUL KALANITHI

A BOOK REVIEW BY ALICE KAY
POLICY AND COMMUNICATIONS GROUP



As has been well documented, this is a book about death. There has been a small surge in books focusing on the realities and inevitability of death in recent years, but many of those books have been from the perspective of individuals who deal with death in their jobs and everyday lives. *When Breath Becomes Air* is a unique and deeply moving take on the subject, as not only does the author regularly deal with death in his role as a neurosurgeon, but he is forced to confront his own impending mortality when diagnosed with lung cancer.

Paul Kalanithi's exploration of illness and death is masterly, frank, and insightful – the reader feels the pain of a successful life cruelly cut short, but is also brought on a journey towards reconciling this pain with the inevitability of death. By the final pages, the author feels at peace with his lot and the reader in turn feels the same. Threads of humour and dark observations run throughout the book, and the language is elegant and moving without being sentimental. You can't help wish that Kalanithi had lived long enough to write more books.

When Breath Becomes Air is divided into two parts that neatly juxtapose the author's life pre- and post- cancer diagnosis. In the first part, Kalanithi is training as a neurosurgeon, and describes the ordeal of working endless hours to gain the necessary skills and experience to land a prestigious neurosurgery/neuroscientist job at a top institution: his ultimate goal. The sacrifices this requires – a common theme across many medical careers – is clear in every page, although the effort is balanced by Kalanithi's abundant passion for neurosurgery. It's apparent that he will progress right to top of the medical tree.

It wasn't to be. The second part of the book reveals the completely different ordeal of coping with cancer. Kalanithi's honest descriptions of his illness are harrowing as he details its advance and the symptoms he suffers. Readers feel that disaster has been averted when the drug Tarceva successfully slows the growth of the cancer, allowing Kalanithi to recover somewhat and return to the operating theatre.

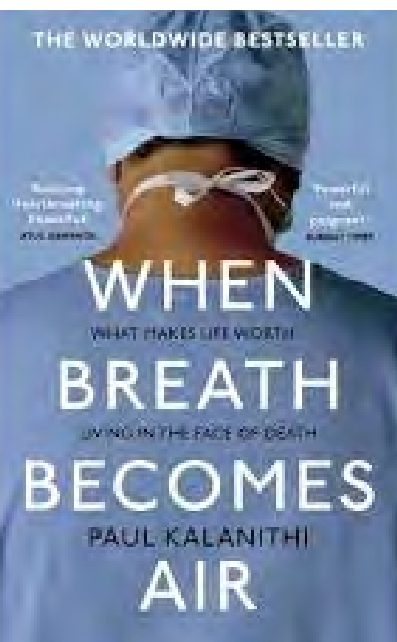
There is even a vein of hope running through these pages: perhaps Kalanithi has a long-term future as a neurosurgeon after all? There are moments of reality that threaten to dismantle this dream. In one instance, Kalanithi is being wooed for a prestigious job in Wisconsin, when he suddenly realises that the idea of him and his wife moving away from their support network and the doctors who are treating him is a fantasy.

A particularly heart-breaking moment is when Kalanithi is abruptly faced with the reality that his cancer is too advanced to permit him to carry on as a neurosurgeon. He performs a final surgery and then leaves the hospital for the weekend, never to return as a doctor. After the gradual advance of his illness and the fortitude Kalanithi showed in adjusting to his physical limitations and continue operating, this blow feels sudden and harsh. The book makes it clear that Kalanithi had reconciled himself to the idea that he would have to leave his career if the cancer worsened, but one has to wonder whether he was expecting that decision to come so soon – it certainly feels sudden to the reader. The subsequent decline in his health feels rapid, although it's clear that Kalanithi makes the most of his life and doesn't shy away from the new realities of his illness.

A driver for Kalanithi's changing priorities is his wife's and his decision to become parents. By the time their daughter is born, Kalanithi's health has declined considerably, but this brief time with his child feels precious and endless, rather than frantic and sorrowful. Kalanithi's final words are addressed to his daughter, and they implore her to know that she filled his last days with immense joy and left him content.

The final pages in the book are an epilogue from Kalanithi's wife, Lucy. Her thoughts are beautifully and eloquently laid out, while posing a sharp contrast to Kalanithi's chapters. Her description of his death and the events afterwards serve as a stark reminder to the reader that the author is no longer with us, and while the dying may find their peace the living have to continue without their loved one. Yet, Lucy's words also provide a beautiful third person perspective of her husband to complement his own self-reflections throughout the book. By the time you reach the final pages, you may well have a tear in your eye, but you will also be comforted by the knowledge that Kalanithi died a loved and fulfilled man.

Above all, *When Breath Becomes Air* is an honest book, and essential reading for anyone who has ever dwelled on the idea of dying (I would imagine that includes most people). I doubt that many people would be able to distil their thoughts on mortality in such a profound and poignant way.



NEWS

UPDATE ON FPM STRATEGY

Following the initial strategy review in October, in January the FPM Board of Trustees was presented with a report on the ideas and the process by which they were selected. You will remember that the strategy review included many members as well as the Board. The Board's advice then was to ask us to focus on implementation and on how to get the best input and guidance from the FPM membership. As a result, we focussed on giving more authority and accountability to the committees, in order that their ideas are given due consideration and can be effectively developed and challenged.

The committees have now been given sessions to directly report to the Board, the first was made this month on Thursday 16th of May, by the Policy & Communications Group. Also in this meeting, the Board approved plans to initiate elements of the strategy and governance review. The committee chairs will also join officers' (president, vice-president, CEO, treasurer and registrar) meetings, which take place 8 to 10 times a year and enable executive decisions. The Ethics and Practice Committee remit will be extended, with a greater focus on developing standards of practice and supporting the FPM membership. The Registrar will carry out a review of our governance documentation. We will also establish a new Strategy Oversight Committee to ensure that the financial and reputational risks associated with projects and plans are properly managed. This will be chaired by a member of the Board of Trustees, David Jefferys.

Detailed descriptions and the opportunities that these changes to the committees will provide will follow in

bulletins over the next few months. The objective is to enable better reporting from the committees to the Board and clearer direction from the officers and chairs of the committees but with greater input for the FPM membership through the committees. Do let us know if you have any feedback or comments.

NEW FPM STAFF



MARCIA PHILBIN will become the new Chief Executive on the 24th June 2019.

"I am delighted to be appointed as the new Chief Executive for the Faculty of Pharmaceutical Medicine. I look forward to working with the Officers, Trustees and staff to implement the new strategy that will deliver growth, innovative educational programmes as well as ensure that the FPM is well positioned to respond to the future challenges facing our members."



BEN FRITCHLEY is the new FPM Revalidation Support Co-ordinator. Ben initially joined us on a temporary basis but swiftly proved himself a vital member of the team and we were delighted to make him permanent in April 2019.

PMST CURRICULUM 2020

KONRAD OBIORA, SPECIALTY TRAINING MANAGER

The FPM has just launched a consultation on its draft specialty-specific and generic capabilities for its new Pharmaceutical Medicine Specialty Training curriculum. The FPM would like to hear from pharmaceutical physicians enrolled on the PMST programme, Educational Supervisors and Associate Educational Supervisors, local education providers and bodies that represent patients and the industry. The consultation process is part of the FPM's project to write a new specialty curriculum for the General Medical Council to approve in 2020. Keep an eye of the FPM [website](#) for further updates.

CERTIFICATE IN PHARMACEUTICAL MEDICINE

We recently announced that individuals who pass Part 1 of the Diploma in Pharmaceutical Medicine (DPM Part 1) will now be awarded a Certificate in Pharmaceutical Medicine (CPM).

DPM Part 1 is the multiple-choice question part of the DPM examination and tests candidates on the core concepts of pharmaceutical medicine. Offering a stand-alone CPM gives individuals an opportunity to demonstrate their knowledge of the fundamental pillars underpinning our specialty. [Find out more.](#)

VOLUNTEERING WITH THE HUMAN RELIEF FOUNDATION

SUE BROOK

Sue Brook, Pharmaceutical Physician at Cancer Research UK and ex-FPM Trainees Committee member, travelled to Jordan last November with a group of volunteers from the charity Human Relief Foundation (HRF), after raising £4,000 for refugees residing there. Sue was part of a team of approximately 25 UK volunteers and HRF employees who, for one week, helped distribute food sacks, meat parcels, winter clothes, hygiene packs and blankets. The main recipients were from Syria but there were other families from Yemen and Iraq.

"The days' activities were very well organised and carefully planned. We visited a warehouse where the food sacks were assembled and helped to pack them; we visited different parts of Amman to distribute the food at designated centres; we helped out with a funday for orphans; we visited refugee families in their homes and listened to their stories and needs and we also travelled to Za'atari refugee camp, home to 80,000 refugees."

"What really struck me was the lack of free healthcare. These families were often making a decision between paying for medicines or paying for rent."

Sue visited The Hope Centre, a rehabilitation facility in Zaatari Refugee Camp for children who have escaped the war. The centre provides physiotherapy, hearing, speech and psychological support.


"We met a young boy who had cerebral palsy who was walking with the help of a walking aid. We learned that six months before, he was unable to walk at all, so seeing him so mobile must have been incredibly rewarding for the team at the Centre. Of course one hears about the situation in Syria in the media, but to actually meet and talk to families who have fled the war and hear their stories and hopes was indescribable. I would love to be able to go back to Jordan with the charity. I would 100% recommend this experience to anyone; it is one you'll never forget."



To find out more about the Human Relief Foundation and to make a donation visit www.hrf.org.uk.



ANNUAL REPORT 2018 - Read it in full


Faculty of Pharmaceutical Medicine
ANNUAL REPORT 2018



600	27	3000		52	
appraisals completed	new DPM awardees	followers on LinkedIn	UG course at BSMS*	members contributing to new PMST curriculum	comments in the media by FPM Expert Groups

*Brighton and Sussex Medical School

2019 at a glance...New website, Annual Symposium, New Chief Exec, FPM Conversations, Business Skills workshops...



EXPERT GROUP UPDATES

FPM Expert groups were formed in autumn 2018 to reactively and proactively input into FPM consultation responses, requests for advice and engagement with the press and media. Each group has a chairperson who facilitates and collates the responses from individual members of the groups. The expert groups work closely with members of the FPM Policy and Communications Group (PCG) and Policy and Communications Manager to finalize responses in a timely and efficient manner.

1. Government and Healthcare policy
2. Gene therapies and innovative technologies
3. R&D
4. Paediatrics and other vulnerable populations
5. Primary therapeutic areas
6. Oncology

Here is a taste of some of the work that the expert groups have been up to and their plans for the future...

2. GENE THERAPIES AND INNOVATIVE TECHNOLOGIES

CHAIR: ROHIT BATTA FFPM

The gene therapies expert group are currently considering the draft EMA Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells. They are also working on the storyboard for a short animation explaining gene therapies.

4. PAEDIATRICS AND OTHER VULNERABLE POPULATIONS

CHAIR: RAJA RAJARAM MFPM

The paediatrics expert group have circulated the recent draft EU legislation on medicines for rare diseases and children and are considering a response to the EMA Regulatory Science to 2025: Strategic Reflection.

5. PRIMARY THERAPEUTIC AREAS

CHAIR: CARLO BERTI FFPM

The primary therapeutic areas expert group are currently considering their response to the EMA -Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections.

1. GOVERNMENTAL AND HEALTHCARE POLICY

CHAIR: PENNY WARD FFPM

In addition to press queries concerning medicines supply, this group commented extensively on proposed changes to HMR2012 following Brexit: most of the suggested revisions were accepted. Recently they provided input on Public Health priorities to SCHOPR. Currently they are responding to EMA on their Strategic Reflection: Regulatory Science to 2025 and development guideline consultation requests.

6. ONCOLOGY

CLAIRE BARTON FFPM

The Oncology expert group kicked off with a rapid response to a BMJ article entitled, "Reporting harms more transparently in trials of cancer drugs". Although they agreed with many of the sentiments expressed in the article, they did not agree that use of descriptive terms (such as "manageable" or "tolerable") automatically indicates a down-playing of harms, and felt that analysing individual words and phrases out of context in journal articles was oversimplistic and potentially misleading (like saying that the term "pensioner" or "teenager" was automatically ageist and should be eliminated from all newspaper articles).

Enthused by their first venture, the Oncology expert group is on the lookout for more publications where they might have special insight or expertise to offer. They also plan to review the upcoming revision to EMA guidelines on the evaluation of anticancer medicinal products in man. They would be very pleased to be alerted to any publications of relevance to the group, and for any other suggestions for their activities.

3. R&D

CHAIR: ROB VAN MAANEN

In the first months of 2019 the group's activity involved various consultations. The Royal College of Physicians invited input on the bold and ambitious research questions and drivers of health that will help address the big public health issues, and how the RCP can support novel and bold visions of future transdisciplinary public health research. FDA invited comments on the draft guidance on rare diseases, and EMA invited comments on their Strategic reflection on Regulatory Science to 2025. The draft EMA guidance on development of antimicrobial drugs is currently being evaluated.

They are considering the strategic advantages of expanded access plans (EAPs) and how to leverage these into CDPs. The idea is to collate knowledge about the various EU-nations EAPs, potentially culminating in a publication with relevance for people designing CDPs/ trials. There may even be possibilities to address important inhibiting discrepancies and facilitate international alignment of requirements.

WESTMINSTER HEALTH FORUM POLICY CONFERENCE: PHARMACEUTICAL PRICING AND ACCESS TO MEDICINES

25TH APRIL 2019

MEETING REPORT BY STUART DOLLOW, FPM TRUSTEE



I was pleased to be invited to speak at the Westminster Health Forum policy meeting on pharmaceutical pricing. The meeting included expert speakers and interested bodies on the theme of the new PPRS (Pharmaceutical Price Regulatory Scheme) and its impact across medicines pricing, supply and access.

The meeting was opened by Baroness Jolly (Liberal Democrat Lords Spokesperson for Health) who reflected on the delicate but important balance between access to medicines, and the sustainability of innovation. She introduced Robert Kettel who provided the Department of Health and Social Care's (DHSC) position that the PPRS as a voluntary scheme had to balance sustaining industry and its innovation, while providing access to priority medicines. Managing overall revenue growth rather than regulating individual medicines allowed transparent and free pricing at launch, even if there were less transparent discounts to achieve QALY thresholds. This is a key factor for industry as strongly reflected by Paul Catchpole and David Watson from ABPI. They noted PPRS is a local solution to a global issue with global impact, but that maintaining growth for the industry was vital. The ability to cap that growth under the volume agreement through the industry rebate was agreed as key to the success of the scheme. This session provoked questions on how appropriate it was to have confidential commercial deals that did not allow full price transparency, and how small companies could manage rebates across only one, or very few, products.

The next part of this session included presentations on the legal framework, navigating health outcomes, a single company view (Roche) and an NHS Trust. The take home messages here were that the European Network for Health Technology Assessment (EUNetHTA) played an increasingly important role in helping harmonise evidence requirements for value assessment, even if individual countries applied different thresholds for affordability and value. In addition, outcomes based contracts for medicines and risk sharing would be worth exploring further to increase the range of models available. There was some praise for the Accelerated Access Collaboration concept, but also recognition that its scope and impact were limited and that it was not pushing the boundaries as much as had been hoped.

Fig 1: Anne Marie Morris MP opens the second session.

On the panel: Prof Paul Workman of the Institute of Cancer Research & Dr Stuart Dollow

Bhulesh Vadher (Clinical Director of Pharmacy at Oxford University NHS Trust) presented the complexities of the numerous schemes for early access. From MHRA's Early Access to Medicines Scheme (EAMS), through Compassionate Use, Named Patient Supplies and Expanded Access, each manufacturer has different legal arrangements, all of which adds bureaucracy. He reminded us that there was a patient at the end of each of these schemes, requiring information and consent which takes time and resource to manage.

The second session was chaired by Ann Marie Morris MP (Chair - All Party Parliamentary Group on Access to Medicines and Medical Devices). I participated in this session with Paul Workman, CEO of the Institute of Cancer Research, Nick Medhurst from the Cystic Fibrosis Trust and Mike Hannay from East Midlands Academic Health Science Network (AHSN).

Consistent themes from our talks were the increasing personalisation of therapy in life limiting diseases, and the need for innovation to be sustainable and affordable. In the case of cancer, paying a premium for a 3 month survival benefit was not seen as sustainable, especially when cancer resistance patterns evolve to make even some of these new therapies ineffective. The plea was not for multiple products targeting the same mechanism, but for more diversity in targets to allow novel combinations to be tested in more targeted real-life studies such that they were affordable in clinical use. In the Cystic Fibrosis area even with protracted negotiations, three years' delay to access for Orkambi has meant substantial avoidable morbidity and mortality, although its use would have come at a substantial premium.

I discussed similar themes of ever smaller patient populations through personalised therapy with more complex products acting on unprecedented mechanisms. While these increase costs and risks, the need to properly assess safety, quality, efficacy and cost effectiveness is as high as ever. These, including pipeline failure costs, drive the need for cost recovery, but in a manner that is affordable for healthcare systems. Several of us proposed opportunities to reduce development times and shorten the time to approval, leading to initial use in restricted populations with ongoing data collection to accrue evidence on benefit:risk as well as effectiveness. The reduced investment would allow lower prices at launch, but these would rise as evidence of outcomes emerge and the indicated population expands.

The final presentation was from Meindert Boysen of NICE. As NICE does not have time or resource to assess all new technologies, he proposed an 80:20 rule. 80% of technologies were reasonably predictable and could be assessed through a simple standardised [automatable?] process, whereas 20% require more in-depth evaluation and could be reviewed in detail. He recognised PPRS played a very important role, although the underlying theme was that sustainability can only come from a more disruptive approach.



NEW TECHNOLOGIES AND THEIR IMPACT ON MEDICINES AND DEVICES DEVELOPMENT

Introduction

18 months ago, Sir John Bell published his report on the UK Life Sciences Industrial Strategy^a. In it he set out a strategy which over 20 years could take the UK to a position of global leadership in the Life Sciences. One of the key drivers he identified was the need to increase collaboration between the NHS and Industry, and for both sectors to take full advantage of new technologies by increasing skills in this area. Highest on the list is knowledge in the use of genomics to define the molecular mechanisms of both common and rare diseases.

Within 6 months of Sir John's report the ABPI published their Skills Gap^b in medicines development and it was quickly followed by the NHS-sponsored Topol Report^c, both of which place a much greater focus on developing the skills of the life sciences workforce in both industry (pharma and tech) and NHS.

New skills are required in data management, along with augmented intelligence and statistics, to cope with the massively expanding whole genome sequencing (WGS) field and in managing the continuous recordings of vital observations from patients using digital devices.

Two examples have been chosen to illustrate the potential opportunities for us pharmaceutical physicians. One is an example of a disruptive monitoring diagnostic for patients with chronic disease, which draws together devices and augmented intelligence (AI) to provide an inexpensive monitor for chronic illness. The other is the use of genomics, digital medicine, and AI to uncover a common genetic abnormality hitherto not linked to disease. What is even more interesting is it illustrates how these techniques also identified genetic loci that appear to modify the risk of developing disease, indicating new ways to identify novel therapeutic targets and diagnostics.

The next steps for digital monitoring from "wearables" to remote Photoplethysmography

The merchandising websites like Amazon, the Apple Store and Google offer a wide range of devices that you can wear including, watches and rings, that can monitor blood pressure, heart rate/ECGs and blood gases and glucose levels. Indeed, these are being connected to cloud-based systems that can continuously record data and build patterns through algorithms which undertake timeseries analysis to predict onset of exacerbations or flare ups of chronic diseases. They are being used to monitor illnesses such as hypertension, asthma/COPD and inflammatory diseases like rheumatoid arthritis. Sadly, often without precise valuation studies to prove clinical effectiveness.

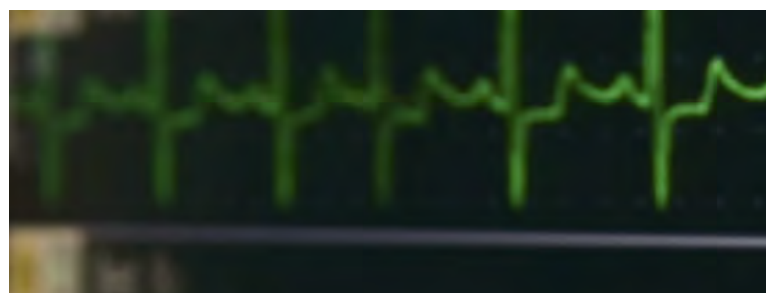
However, a really cutting-edge technology has emerged that is called remote Photoplethysmography (rPPG), that can provide measurements of vital signs at low cost without the inconvenience of wearables or manually logging data. Using only a standard digital camera or tablet plus advanced software in the "cloud", the system can detect a user's vital signs by observing tiny changes in skin colour that are associated with each heartbeat and each breath.

When the smart phone or tablet is opened and the user stares at the screen, in a few seconds, the software detects changes in skin colour each time the heart beats and during each breath. The algorithm in the cloud enables detection and records the pulse rate, the respiratory rate, the blood pressure and oxygen level. It requires no special equipment or training, just the existing software of a smart phone or tablet. If proved to be successful it could solve many of the issues of compliance experienced with wearables. For those who are "techy" a good patent to read is '*Robust and automatic remote photoplethysmography*'^d.

Use of Genomics, Digital Medicine and Augmented Intelligence to discover "molecular therapeutic targets" – an introduction to the new world of medicines discovery

The development of medicine in the 20th century depended on the detailed phenotyping of diseases together with understanding their natural history. Now the focus is on underlying causative molecular mechanisms. Such new therapeutic targets for medicines have been characterised in diseases with single gene mutations, such as cystic fibrosis (CF) discovered by linkage analysis in families with the disease. Great success has been seen resulting in prolonged life in CF patients using small molecules therapies to reduce the deficiencies critical proteins.

The opportunity is now to consider complex diseases where familial associations have not been described. This comes about by using using whole genome sequencing (WGS) which, when combined with genome wide association studies (GWAS) unique genetic abnormalities have been associated with a disease. Furthermore, linked genetic loci can be found that modify the risks of occurrence of the disease.



PROFESSOR TIM HIGENBOTTAM

PRESIDENT, FPM



This type of study determines if the allele of a genetic variant is more common in a phenotype of interest than in a control population. This requires large numbers of patients who have been accurately diagnosed with a precisely defined phenotype. Such work depends on big Biobanks of human genetic material, an important illustration of the value of the UK NHS 100,000 Genomes project. Over a period of three years 97,510 individuals' samples were collected for WGS. These included samples from 69,379 patients with rare diseases, 28,131 from patients with 24 types of cancer. The population was ethnically diverse, with 1/3 non-white patients. The future UK National Genomic Medicine Service is planning to deliver GWS in 1 million patients by 2025.

Genome-wide association studies (GWAS) provide a method to determine the risk of developing a disease with certain genes and how more common variants can modify this risk. Work in this area now uses WGS with enormous data sets from accurately phenotyped patients, then making a comparison with a similar large control population. A recently published study "Genetic determinants of risk of developing pulmonary arterial hypertension..."¹⁶ exemplifies this approach and involves most of the patients with pulmonary arterial hypertension for whom no genetic linkage can be found.

Whilst pulmonary arterial hypertension (PAH) afflicts some 6,500 patients in the UK, only about 4% have a heritable form (HPAH). There are some 350 mutations of one such gene, the bone morphogenetic protein receptor 2 (BMPR2) gene. It is inherited in an autosomal dominant. The mutations tend to either disrupt the production of the BMPR2 protein or reduce its signalling capability. Some other rare mutations have been discovered in families with HPAH and include BMPR1B, CAV1, KCNK3, SMAD9, and TBX4. In terms of specific therapy, no genetic mechanism has been found.

A further point of special interest is that amongst the people who inherit the mutated HPAH genes only about 20% develop the disease. Other factors and potentially other genes alter the risks of the developing the disease. Genes not associated directly with PAH now being recognised to alter the risks of developing the disease. Similar associations have been seen in other heritable disease such as type 1 diabetes and certain auto-immune diseases.

GWAS studies work - following principles

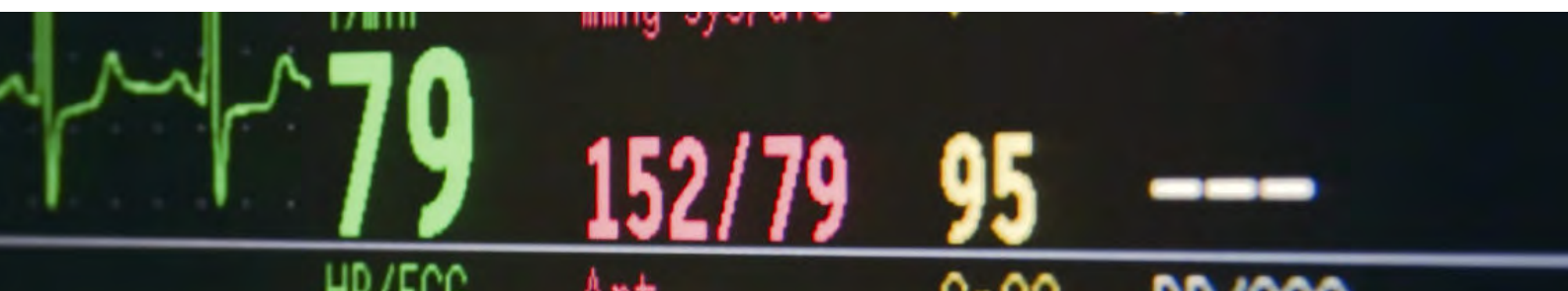
To carry out a genome-wide association study, researchers use two groups of participants: people with the disease being studied and similar people without the disease. Researchers obtain DNA from each participant. This calls for specific clinical skills to ensure that only those patients with the specific characteristic phenotype are included and the controls have no such characteristics.

Each person's complete genome is then purified from the blood or cells, placed on tiny chips and scanned on automated laboratory "next generation" sequencing machines. The machines quickly survey each participant's genome for strategically selected markers of genetic variation, which are called single nucleotide polymorphisms, or SNPs.

If certain genetic variations are found to be significantly more frequent in people with the disease compared to people without disease, the variations are said to be "associated" with the disease. The associated genetic variations can serve as powerful pointers to the region of the human genome where the disease-causing problem resides.

However, the associated variants themselves may not directly cause the disease. They may just be "tagging along" with the actual causal variants. For this reason, researchers often need to take additional steps, such as sequencing DNA base pairs in that region of the genome, to identify the exact genetic change involved in the disease.

In a paper entitled "Genetic determinants of risk of developing pulmonary arterial hypertension..."¹⁶ researchers used four databases with genetic data and accurate phenotypes to provide data for 11,744 individuals with European ancestry (including 2085 PAH patients). One GWAS used 5895 patient data from high throughput WGS and the other used conventional genotyping array data in 5849 individuals. To bring together the two sources, meta-analysis statistics was undertaken to cross-validate loci reaching genome-wide significance. Similar methods of conditional analysis were used to resolve signals for multiple associations.



The main discovery database was the UK National Institute for Health Research Biorepository (NIHRBR) Rare Diseases study. Whole genome sequencing (Illumina, San Diego, CA, USA) was done in 5895 individuals of European descent, each with a rare disorder from 16 categories or their unaffected relatives, and 847 had pulmonary arterial hypertension. The concept of this study was to sequence patients with rare diseases to identify genetic influences on the pathogenesis of one rare disorder using the other rare diseases as controls, assuming that distinct rare diseases are highly unlikely to share common genetic mechanisms. This assumption was tested by repeating analyses excluding each major control group.

Three studies used genome-wide genotyping arrays were also used: the US National Biological Sample and Data Repository for Pulmonary Arterial Hypertension (also known as PAH Biobank [PAHB]) study included 694 individuals with pulmonary arterial hypertension and 1560 controls ascertained for a large pharmacogenomic study at Vanderbilt University (Nashville, TN, USA); the Pulmonary Hypertension Allele-Associated Risk (PHAAR) study included 269 individuals with pulmonary arterial hypertension and 1068 population-based controls from France; and the British Heart Foundation Pulmonary Arterial Hypertension (BHFAH) study consisted of 275 individuals with pulmonary arterial hypertension and 1983 population-based controls from several European countries. Individuals from NIHRBR, PHAAR, and BHFAH were tested for relatedness to prevent inclusion of the same or related individuals across studies.

Results

The transcription factor SOX17 was found to be linked with 59% of patients with iPAH. This provides a new

target for treatment of the disease. Two other loci, one close to SOX17 and one within the HLA-DPA1/DPB1, modify the age of occurrence of the disease and the survival chance once the disease has developed, whilst not being linked directly with the disease.

The 'next generation' whole genome sequencing coupled with augmented intelligence and data handling of accurately phenotyped patients plus the clinical skills of the physicians involved led to these discoveries. They were achieved through a massive international collaborative effort, and they are helping to open the way to developing new therapies that target the defective alleles or potentially the disease modifying loci.

What can we conclude from these simple illustrations?

Our industry is perhaps entering one of its many transformations, which is likely to be exciting and challenging. As members of the FPM - an organisation that is committed to advancement of science and achievement of quality - there is much for each of us to do in learning the necessary new skills.

References

- a) [UK Life Sciences Industrial Strategy](#)
- b) [The ABPI Skills Gap Report](#)
- c) [The Topol Review](#)
- d) [Robust and automatic remote photoplethysmography](#)
- e) [Genetic determinants of risk of developing pulmonary arterial hypertension](#)

FPM PAST-PRESIDENT, PROF ALAN BOYD TO GIVE A PRESENTATION FOR RCP MEDICINAL PLANT LECTURES: JUNE, JULY, SEPTEMBER 2019

Mon June 10th

2pm - Prof Alan Boyd 'Botanical origins of pharmaceutical medicines'

3pm - Tea and Tours of the Medicinal Garden by the Garden Fellows

4pm - Prof Stuart Anderson 'Colonial Medicinal Plants and Pharmacopoeias of the British Empire 1837 to 1932'

4.45-6.30pm - Book launch - Pharmacopoea Londinensis of May 1618 in facsimile, with refreshments

Mon July 15th

2pm - Dr Lisa Lodwick 'Box, Beer and Barley: Archaeobotanical evidence from Roman Britain'

3pm - Tea and Tours of the Medicinal Garden by the Garden Fellows

4pm - Dr Noel Snell 'Medicinal aspects of coffee, tea, and chocolate'

Mon Sept 9th

2pm - Dr Richard Bisgrove 'The Little Garden and the Great Herbal: medicinal plants in the medieval garden'

3pm - Tea and Tours of the Medicinal Garden by the Garden Fellows

4pm - Dr Ann Ferguson 'Plant poisons for arrows and harpoons'

Garden website: <http://garden@rcplondon.ac.uk>

Podcasts: [https:// soundcloud.com/rcp-garden](https://soundcloud.com/rcp-garden)



HOW I FOUND MYSELF IN PHARMA

DR SHARON MCCULLOUGH
CONSULTANT PHARMACEUTICAL PHYSICIAN



If anyone had told me when I was a junior doctor that I would eventually find a medical specialty that I loved I would never have believed them. Medicine had always seemed like being in a foreign country without a map. With no medicine in my family and A-levels that included English and Economics but not Biology I had muddled through. I had wandered into GP training, but the prospect of partnership and a lifetime in a single practice was becoming claustrophobic.

And then I enrolled on a writing course run by Tim Albert, ex-Mirror journalist and editor of the BMA News Review. I got an article published in the Spectator, Tim offered me a job as News Editor and I made the transition to office work. It was a fantastic opportunity – a completely liberating gateway. I learned about publishing and writing, and how the NHS worked. But eventually having to toe the BMA party line and the passive nature of reporting became irritations. Learning beckoned (as it should, given that my Mum was a teacher).

I'd overheard a conversation on a train about MBAs. Dad was in sales at Mars and the world of business and the bottom line seemed a welcome contrast to the huge, politically driven healthcare system I'd trained in. And the NHS was changing – purchasers and providers were new buzz words. And business school was fun. I met people with roles very different to my own and I learned some useful tools and tricks. But the biggest learning was that business is only applied common sense. I still wonder whether anyone really needs to go to business school to learn that.

Then it seemed like time to find a 'proper job'. Living in Uxbridge I'd seen the redevelopment of the Stockley Park landfill site and heard that the new buildings going up were for Glaxo. Eventually, after battling a headhunter who told me I was completely unsuitable for the role, I was appointed as a medical adviser (forever thanks, Francis Upchurch and John Hall). And so began five years of fantastic UK operating company experience. Despite the MBA it took a long time to make sense

of this strange new world. There was no PMST curriculum then to guide me. I worked my way through the medical department, collecting experience in pharmacovigilance and post-marketing safety studies, completing the Dip Pharm Med, undertaking a marketing secondment and running a field-based team. But eventually - or as I was now beginning to understand, for me, inevitably - the organisation became stifling. So I took a role with Innovex, a contract research and sales organisation (now subsumed via Quintiles into iQVIA).

Innovex was also a marketing authorisation holder with its own small product portfolio and commercial team. I learned about pitching for business, supporting clients, and about being a small-scale medical director. Then, just as I was getting bored, the opportunity to contract myself out of the company came up and my employer became my very first client. And ever since then I've worked for myself, providing medical affairs and pharmacovigilance physician services.

Working with the ABPI Code of Practice brought opportunities to provide training, setting me on an educational journey of my own: a post-graduate teaching certificate; a professional doctorate (still underway!); and FPM committee work and Educational Supervisor activities. A fascination with standards and professionalism, what it means to work in a regulated environment, and how Good Medical Practice maps onto pharmaceutical medicine, have led to Appraiser and Appraisal Lead roles. I owe Peter Stonier and Susan Bews huge thanks for those opportunities.

It probably sounds like a very haphazard career. Certainly none of it was planned. But with hindsight I can see that by building a personal route map based on my own interests and values I have eventually arrived at a place that really feels like home. Pharmaceutical medicine still welcomes wanderers from all sorts of places, and long may it do so. How fortunate I am to have found myself in pharma!

Feedback and ideas

We really value your feedback and comments on the *Journal of the Faculty of Pharmaceutical Medicine*. Please let us know if you have any general comments or ideas for future issues, or would like to contribute a particular article.

Reflection and learning

Have you learned something from this edition of the Journal? If so, why not use it as CPD for your appraisal?

You'll need evidence (take a screen shot) and reflection (a couple of paragraphs on what you learnt, what effect it will have on your current practice and how it relates to Good Medical Practice). Upload it into your portfolio and self-allocate your CPD points at 0.25 credits per 15 mins. Easy!

More information here: https://www.fpm.org.uk/revalidationcpd/CPD/cpd_guidance_june_2014

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