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PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: INSIGHTS FROM ACADEMY ALUMNA

BY DR. RACHEL LAWSON

We continue with our Professional Identity and Medicines Development series. Below is an essay written by Dr. Rachel Lawson. The Academy is grateful to Dr. Lawson for her continued contributions to our learning community.

She responded to the prompt, "Discuss the development and status of your own Professional Identity and what it means in terms of your job, your career, and future prospects."
See page 2.

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"Participating in the Academy course has been a welcome opportunity. Through the modular approach I have been reminded of things I have done, but long forgotten, learnt new things and, importantly, learnt the rationale behind what we do. Often in our fast-paced, reactive world the rationale and justification get hidden. The formal education delivered in the form of lectures and assignments have therefore built my expertise and afforded me the knowledge to shift my professional identity to that of a medical affair professional. A greater understanding of elements such as health economics, which I had little previous exposure to, have been very useful and timely. I found that many of the elements I learnt I could directly incorporate into my work and this in turn reinforced my professional identity.

Course participation has involved not just the formal learning tasks. Through the discussion groups and interactive webinars, it has allowed me to gain exposure to other peoples' views. Their shared experiences, different perceptions, understandings, and interpretations have also been very influential. I have welcomed the more interactive nature of these items. Points are raised that I had not even considered, and the weight placed on certain aspects by others has made me pause and reassess how I look at things. These informal interactions have contributed to the process of socialization, a key part of developing a professional identity (Cruess et al., 2015).[1]

As my career progresses and I take on more leadership roles this is a skill and a professional attribute that will continue to develop. I found it interesting in the course how the role of medical affairs has the key concern of keeping the patient at the centre of activities. This resonates with me and is a strong part of my professional identity."

Rachel's interest in Medicines Development dates back to her undergraduate days and prompted her to take up her first industry position as a development chemist at GlaxoSmithKline whilst studying for her undergraduate degree. Following her PhD and working as a research fellow in the UK and USA, Rachel initially moved into clinical research in the National Health Service before returning to industry in clinical operations. Five years ago, she had the opportunity to join Sanofi in Medical Affairs. She enjoys the patient-centricity and diversity of medical affairs activities and finds product launch activities particularly exciting. She found participation in the IFAPP course and the opportunity to meet virtually with other medical affairs professionals to be both valuable and enjoyable.

To read the essay in its entirety, please click here.

PRESCRIBING OPIOIDS FOR PAIN- THE NEW CDC CLINICAL PRACTICE GUIDELINE

One of the biggest challenges in medical practice is the treatment of chronic pain. Pain affects the lives of millions of Americans and potentially reduces their level of function, mental health, and quality of life. Yet limited access to pain treatments and lack of clarity regarding the evidence supporting pain treatments prevent many people with pain from accessing the full range of potentially helpful therapies.

Furthermore, there are persistent disparities in pain management according to race or ethnic group, gender, socioeconomic status, and population density, among other factors. Opioids continue to be commonly used to treat pain, despite evidence that their short-term benefits are small and despite limited evidence of long-term benefits.

In 2016, the Center for Disease Control and Prevention (CDC) released its Guideline for Prescribing Opioids for Chronic Pain to help primary care clinicians weigh benefits and risks of opioid treatment for chronic pain. The guideline's release was associated with accelerated reductions in overall and potentially high-risk prescribing of opioids and with increases in prescribing of nonopioid pain medications. Keep reading here.[2]

NEWS FROM THE EMA: VIRAL SAFETY OF BIOTECH PRODUCTS

The European Medicines Agency has published for public consultation an ICH Guideline Q5A(R2) on viral safety evaluation of biotechnology products derived from cell lines of human or animal origin. This guideline concerns the testing and evaluation of the viral safety of biotechnology products, and it outlines what data should be submitted in marketing applications and registration packages for those products.

Biotechnology products include biotherapeutics and certain biological products derived from cell cultures initiated from characterized cell banks of human or animal origin (e.g., mammalian, avian, insect).

Comments should be provided using this template and sent to ich@ema.europa.eu by February 10, 2023.

WHY IS STREP-A SURGING, AND HOW WORRIED ARE SCIENTISTS?

British pediatricians each spring know what to expect: an increase in group A streptococcal infections that should be tail off by the summer. But an off-season outbreak of the bacterial infections this year has jumbled expectations, made scores of people ill and killed 13 children under the age of 15 in England since September. “To my knowledge, we’ve never seen a peak like this at this time of year, at least not for decades,” says microbiologist Shiranee Sriskandan at Imperial College London.

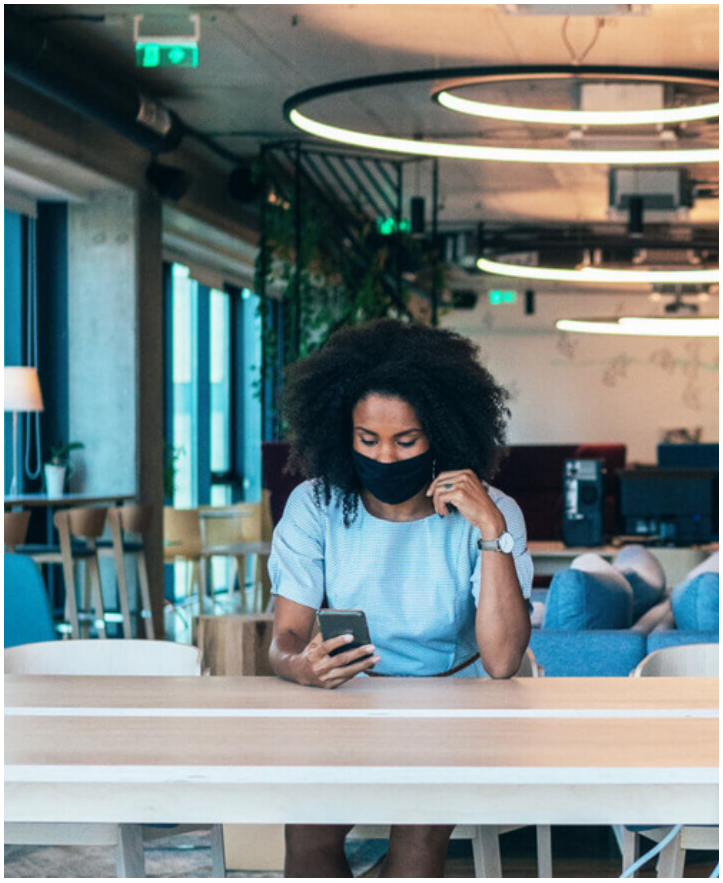
One theory is that lack of exposure to group A Streptococcus (strep A) during lockdowns at the height of the COVID-19 pandemic means that young children lack immunity against the bacteria.

But it is too early to say for certain if this is behind the strep A surge.

“There are a lot of things that seem to be a bit strange happening after the lockdowns. But it’s hard to say whether that’s causing the surge right now, especially given that we have had surges prior to the pandemic.” [3]

Continue reading here.

COVID-19: UNIVERSAL AND INDIVIDUAL MASKING IMPACTS



Nearly 3 years into the Covid-19 pandemic, the United States leads high-income nations in Covid-19–related mortality. Millions of persons now have long-term neurologic, cardiopulmonary, and other disabling conditions.

Essential workers continue to face high workplace exposure to Covid-19 with few protections. To prevent Covid-19 transmission, 40 states and Washington DC implemented universal indoor masking policies in 2020. Most maintained these policies until May 2021, when the Centers for Disease Control and Prevention (CDC) replaced guidance that everyone wear masks with guidance according to vaccination status.[4]

Continue reading here.

NEWS FROM THE EMA: OBESITY DRUG WITHDRAWAL FROM THE MARKET

Obesity is a global medical issue and one with far-reaching impacts on health and quality of life. As such, many pharmaceutical companies have devoted efforts to research medicines which prevent or reduce obesity and/or weight gain. There are currently two pharmaceutical avenues in the treatment and/or prevention of obesity: Drugs which act in the gut and inhibit fat absorption, and drugs which act at the CNS level to suppress appetite. In past years, many drugs were developed to suppress appetites. However, RWE studies underlined the risk of the latter group, as they were often administered for several months and caused severe adverse reactions.

Recently, the EMA safety committee (PRAC) has confirmed its recommendation to withdraw the

marketing authorizations for amfepramone obesity medicines. This follows a re-examination of its previous recommendation of June 2022, which was requested by the companies that market these medicines.[5]

Continue reading here.

FDA INVESTIGATING RISK OF SEVERE HYPOCALCEMIA

RWE studies are performed when any drug is on the market with two main objectives. The first objective is to confirm the efficacy and safety in the normal population of patients, without exclusion criteria seen in Phase II and III trials. The second objective is to collect safety data from a much larger patient population for the possible identification of immediately rare or very rare adverse reactions. Below is a good example of the identification of a rare adverse event thanks to RWE studies. Of note, this rare adverse event was not identified during the pre-NDA clinical trials.

“The U.S. FDA is investigating the risk of severe hypocalcemia with serious outcomes, including hospitalization and death, in patients with advanced kidney disease on dialysis treated with the osteoporosis medicine Prolia (denosumab). Our review of interim results from an ongoing safety study of Prolia suggests an increased risk of hypocalcemia in patients with advanced kidney disease."[6] Continue reading here.

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Thanks for reading!

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