

Editorial

Happy 80th birthday to I. Ralph Edwards from the editorial board

This special editorial for the Editor-in-Chief of the *International Journal of Risk & Safety in Medicine* (JRSM), Prof. I. Ralph Edwards, prepared jointly by the editorial board members, is meant to celebrate his 80th anniversary.

For the epigraph we would like to use the words of board member Prof. Ambrose O. Isah (University of Benin, Nigeria), and join in the harmonic choir:

“Ralph at 80 is a time to really celebrate a great octogenarian, a clinician cum scientist per excellence, a great role model, a loving family man, an amiable friend loved by many and my much-cherished friend. Congratulations Ralph. Wishing you a really happy birthday!”

We asked our editorial board members to share a few words of celebration and were heartened though not surprised to receive their wonderful responses. We sincerely thank all our distinguished board members for their warm, rich and valued contributions. They have made this editorial such a unique event in the JRSM editorial history.

The contributions make the backbone of this editorial. We hope you enjoy reading these birthday wishes and celebrate Ralph’s dignified anniversary with us.

We identified two themes in the contributions, which equally enhance each other in the celebration of Ralph: The journal (JRSM) and pharmacovigilance.

The journal

For the journal part of the editorial we would like to use the words of **Prof. Carlo Bottari and Dr. Federico Laus**, Associate Editors, our experts in pharmaceuticals policy and law, from the University of Bologna, Italy, as the epigraph:

“With an interdisciplinary slant and free from dogmatic and preconceived positions, the journal has made it possible to examine in depth the most important critical issues relating to the health system and to point out the main dysfunctions, scientific developments as well as some of the most innovative or in any case significant concrete experiences. In this sense, Prof. Ralph Edwards’ leadership contribution was fundamental and the opportunity to wish him a happy birthday and at the same time thank him cannot be missed.”

Dr. Ulrich Hagemann, Editorial Board member, our expert in Pharmacovigilance, representing the Drug Commission of the German Medical Association, Berlin, Germany wrote:

“He engaged me ...

... in many and various aspects. At a couple of meetings and conferences in the past we both listened to reputable speakers who usually attract many listeners. They are something like a safe bet for conferences.

But what about young scientists who still have to find their way to be recognized, heard or read? Frequently, they don't have easy access to publish in renowned journals in particular if their topics are not yet well developed or substantiated. Where and when can they learn to improve their 'messages', their performance and standing?

Ralph Edwards and I had the idea to give young or yet unexperienced scientists a place and time to present their research results in short presentations—junior pharmacovigilantees without any major expectations, pressure and fear 'to be taken to pieces' by an overcritical audience. An open minded atmosphere for respectful questions and supportive comments are needed. At some occasions we initiated successfully sessions for which young scientists were invited, sometimes finally enriched by a simple award.

So, having this in mind, I think, Ralph Edwards asked me someday whether I would like to act as a reviewer and an Associate Editor of this journal, and I agreed. After having taken over this role I learned a lot — either when looking as a reviewer on a typoscript, or as the Associate Editor to manage the review process. Making up my mind and to come to a final decision about acceptance or refusal of a text is challenging. It is so easy to be only a reader of scientific articles not knowing how much work has been invested in a publication and what have been the problems and obstacles along the way.

I would like to thank Ralph Edwards for having hired me for this journal!"

Pharmacovigilance

Prof. Ambrose O. Isah, our expert in medicine and clinical pharmacology, from the University of Benin, Nigeria, recalls:

"It is with great joy that I congratulate Ralph on his 80th birthday. I have known Ralph for about thirty years since participating in the WHO Uppsala Monitoring Centre (UMC) annual Pharmacovigilance course. His personae conveyed an image of authority in the field of Pharmacovigilance and conjured an aura of dignity, humility as he related to the participants in an unassuming, self-effacing manner.

In the field of pharmacovigilance, he is portrayed as a colossus, bringing to bear his scientific prowess with the development of systems and technologies to manage the global data generated by the enormous adverse drug reaction reports. He remains a Giant, a Titan of no small measure who bestriding the world of Medicine Safety has been a captain of a team while as Director/CEO of UMC put in place a mechanism to proactively address potential risks of medicines with the safety valve allowing into circulation safe medicines, and as an ombudsman critically ensuring that their market life is determined by a sustained positive benefit–risk balance.

Prof. Ralph Edwards has been involved in the mentorship of several academics worldwide, training many doctorate students, with his reach strengthened by his books which serves as main texts for students in clinical pharmacology and pharmacovigilance. A keen researcher and prolific author he contributed immensely to the science of pharmacovigilance and the broadening of its scope as attested to by his numerous publications in peer reviewed journals.

With the training course, he provided a platform where he engaged several experts to form a global team dedicated to expounding the concept of Pharmacovigilance. A crop of graduates of this course metamorphosed into a platform developed with his UMC colleagues (Dr Marie Lindquist and Late Sten Olsson) for mainly African experts coined 'Pharmacovigilance sans frontier' which popularised the term 'Pharmacovigilante'. I was a beneficiary of this global thrust. The dividend of this exercise was the establishment of Pharmacovigilance systems in many countries including those in Africa. In essence, Africa benefitted from this scheme with now over 40 countries in the continent in the global watchdog program of the WHO – PIDM. The innumerable lives saved by the use of safe medicines cannot be quantified by any measure.

Ralph is a global figure with legacies dotted all over and has been described as a 'friend of Africa and Africans' and he demonstrated this by getting a number of African countries into the safety monitoring net provided by the UMC thus ensuring safe and effective use of Medicines.

During this period of knowing him, I have appreciated his patience, calmness even in the face of challenging situations, his ever-permanent disarming smile, characteristic mien and love for persons of all race and creed. These attributes resonate in all his decisions and approaches to life, always offering that word of encouragement, that wise counsel, that lingers in one's mind through life. His concern, love and care for humanity was extended to me and family during my near two weeks abduction by hoodlums. Permit me to use this occasion of his 80th birthday to further express my gratitude to Ralph and his beloved wife, Marie Lindquist (Past Director/CEO of the UMC).

Ralph, you remain a global figure, a Patriarch in the field of Medicine Safety (Pharmacovigilance), whose legacies form indelible imprints in the sands of time. The enormous impact you have made earned you the recognition by the University of Benin, Benin City, Nigeria as 'a great scholar-legend who has traversed the continents of the planet in his quest to protect MAN from the harmful effects of medicines', with the award of the revered degree of Doctor of Science (DSc) honoris causa."

Dr. Abimbola Olowofela-Opadeyi, our expert in clinical pharmacology and therapeutics from the University of Benin, Nigeria, takes over and contributes with her thoughts and experiences:

"I first heard of Prof. Edwards from my mentor, Prof. Ambrose Isah; a doyen of pharmacovigilance in Nigeria, and he had nothing but high praise for Prof. Edwards. I then had the opportunity to encounter this great man during my doctoral defence in 2018 when he was a member of my doctoral jury, and just seeing his name on my panel was enough to send trepidations through my heart and brain. How could I impress these great men, who knew the length and breadth of pharmacovigilance, with my research? The defence went really well, and it was great interacting with him and other members of the jury.

When you meet people who have real insight into your field of study as well as your local setting, it feels just right. This was the feeling I had at the end of my defence. He asked a lot of penetrating, thought-provoking questions, and I was still awed by his depth of knowledge about pharmacovigilance despite having seen his profile.

I again had the pleasure of physically hosting Prof. Edwards at the University of Benin when he was honoured with the distinguished award of Honorary Doctor of Science degree (DSc honoris causa) and convocation lecturer in 2019. The feeling you have when you meet a celebrity for the first time—that was how I felt when I met Prof. Edwards then. He derived pleasure from simple things, and you could see that he totally enjoyed the experience. It was a pure delight to have him around and such a great honour for the University and the Department of Clinical Pharmacology and Therapeutics, where I was the acting Head of Department at the time.

Prof. Edwards has been promoting pharmacovigilance for many years. He has dedicated a greater proportion of his life to protecting the lives of others and ensuring that the medicines we all use in one form or another are safe. This is someone worth emulating and celebrating.

As he turns 80, I know he is still going strong, and I wish him many more years of good health.

Happy 80th birthday, Prof. Ralph Edwards."

Prof. Maxine Gossell-Williams, Associate Editor, our expert in pharmacology and pharmacovigilance, from the University of the West Indies at Mona Kingston, Jamaica, shares her memories, experiences and views:

"I first met Ralph in 2009; at the time he was director of the Uppsala monitoring Centre. It was the sponsored workshop in Pharmacovigilance and Basic Pharmacoepidemiology at World Health Organization Drug Monitoring Centre, Uppsala, Sweden and although I was neither directly involved in the regulatory or industrial aspects of the pharmacovigilance network of Jamaica, his facilitation of my training at this workshop was a great start to my many scholarly initiatives. With over a decade of his continued mentorship, including his trust in my capacity to support the work of the International Journal of Risk and Safety in Medicine, I was truly elated to contribute to this editorial.

His lifetime of advocacy focused on improving patient safety is undoubtedly commendable. His unceasing efforts towards highlighting the multidimensional nature of the patient that remains inadequately captured in safety regulatory processes and how this can be improved, has been the focus of a number of his editorial contributions. Through his platforms, he encouraged a change that will foster a greater representation of the patient, such as from the perspective of behaviour and willingness to engage with treatment recommendations. His vision is for a greater inclusion of notes from the doctor responsible for care of the patient as part of the safety regulatory process. With the strides being made to integrate artificial intelligence into the patient safety process, the untapped possibilities of what is referred to as ‘the patient voice’ is a cause I envision remains a priority for Ralph to continue to champion.”

Dr. Mauro Venegoni, our expert in internal medicine and pharmacovigilance from the University of Verona, Italy, recollects and send his thoughts and wishes:

“Dear Ralph, we met for the first time when I was working at AIFA, and together we re-established contacts between UMC and the Italian Agency, which had been interrupted for more than 15 years. Since then our contacts have always continued: a beautiful friendship was born, thanks to Giampaolo Velo, even if we were separated by thousands of kilometres. I shared with you the interest in pharmacology, the passion for people, the hope of favour independent information and promoting the rational use of medicines: I’m not sure that all our objectives have been achieved, but it was exciting to try. We spent wonderful moments together, which I hope will be repeated many more times; for now a big “happy Birthday! With esteem and friendship, Mauro.”

Dr. Priscilla Patricia Nyambayo, our expert in pharmacovigilance and clinical trials, Head of the Pharmacovigilance and Clinical Trials Unit of the Medicines Control Authority of Zimbabwe, sends her warmest thanks and wishes:

“Happy birthday Ralph. Wish you many more blessed years. Thank you for the amazing excellent leadership in pharmacovigilance (PV) globally through technical support to national (PV) centres, scientific community, health care professionals, mentorship, and passion in promoting patient safety. I learnt a lot from your inspiring publications. Thanks a million.”

Dr. Andrzej Czarnecki, our expert in pharmacovigilance and internal medicine, from Eli Lilly and Company, UK, contributes his huge respect and anniversary wishes:

“...[I’ve known] Ralph [since] 1985 when he was still residing in New Zealand. It was 27.5 years ago when we all met and last time for the 40 Anniversary of UMC there were still 7 of us from the original group.”

Dr. John McEwen, our expert in pharmacovigilance and neurology from the Therapeutic Goods Administration, Australia, sends his greetings:

“As a colleague for forty years, I am in admiration of your clinical, writing and interpersonal skills that have made you a global leader in pharmacovigilance.”

Dr. Ruth Savage, our expert in clinical pharmacology and epidemiology from the University of Otago, New Zealand recollects and shares her thoughts and warm greetings:

“Ralph, as you reach your 80th birthday, the words vision, tenacity and advocacy spring to my mind when I think of your considerable contribution to ensuring that pharmacovigilance is truly global. I think also of your willingness to listen to and embrace new ideas leading to the earliest work on statistical analysis of large pharmacovigilance databases. Your wide reading and reflection have generated a number of “thought”

papers, in particular providing a strong theoretical background for practical training in causality assessment. Conversations with you have revealed your background as a competent and caring physician and this aspect has carried through, always reminding us that behind every adverse reaction report is an affected patient and, a concerned clinician. You have also encouraged the closer linkages with organisations that focus on patient safety. Finally, after finding myself in a situation where it seemed impossible for me to return to pharmacovigilance, you found a way for me to do this alongside my clinical practice, a combination you thought was of value, and I will always be grateful. Ralph, I wish you a truly happy 80th birthday and wonderful years ahead.”

Prof. Dr. Michael Tatley, our expert in pharmacovigilance, public health and vaccines, Director of New Zealand Pharmacovigilance Centre, from the Otago University, New Zealand, shares his memories and warm wishes to Ralph:

“Ralph, we are all privileged to reap the benefits of your illustrious contributions to transforming global pharmacovigilance to the form that we all take for granted today. You have a special place in New Zealand pharmacovigilance history when you were the Director of the NZ National Toxicology Group at the University of Otago - comprising the National Poison Centre and Centre for Adverse Reaction Monitoring before you went on to take on the lead role for the Uppsala Monitoring Centre. Under your leadership you elevated the UMC’s global role and became the pharmacovigilance legend you are! Thank you for your passion, insightful and regularly thought-provoking contributions. We and pharmacovigilance are all the richer for it.”

It seems that it is not possible to find better, deeper, richer words to make this day memorable for Ralph, than his life-time colleagues did. May we use the final words of Prof. Ambrose O. Isah’s special message, reshaping it for plural, for all of us to conclude this joint editorial, fully sharing his ideas and feelings:

“To encapsulate Ralph’s dimensions in any tribute is an encyclopaedic task which I [we] dare not attempt. With these few words, distinguished ‘pharmacovigilante’ per excellence, I [we] salute you and admire as you maintain that elegant youthfulness and radiant presence, aging gracefully, into the next decade.”

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