BRAC UNIVERSITY
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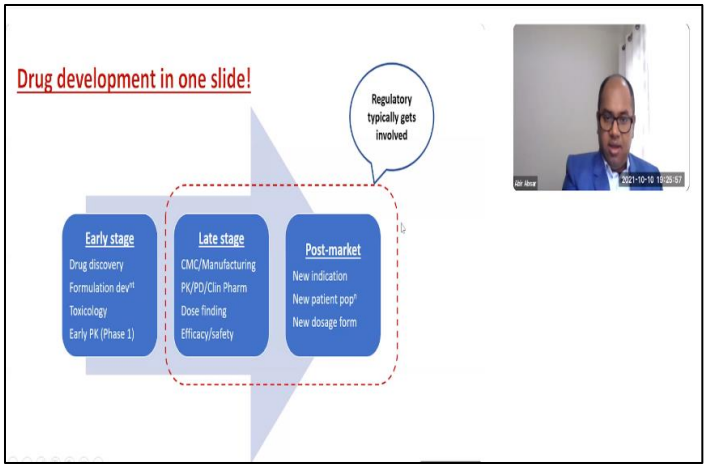
Department of Pharmacy

PHARMA HIGHLIGHTS

ISSUE 85 | OCTOBER 2021

Webinar on 'Regulatory Strategist: An Emerging Career Path in the Pharmaceutical Industry'



Regulatory strategists are an integral part of the drug development process from early preclinical stages through to the post-authorization stage. They help the R&D team within pharmaceutical companies to comprehend the regulatory landscape, expectations from regulatory agencies, competitor activities, recent trends in innovation, etc. to make the development process more efficient and to enhance the likelihood of product approval.

As part of the 'Toolbox for Success' series designed by the Department of Pharmacy, Brac University, a webinar on 'Regulatory Strategist: An Emerging Career Path in the Pharmaceutical Industry' was jointly organized by the Department of Pharmacy and Brac University Pharma Society (BUPS), on October 10, 2021, at 7 pm (Bangladesh Standard Time). The session was held on Zoom for registered students and alumni of the department, and for interested participants from other universities and pharmaceutical companies.

The event was initiated by the welcome speech of Professor Dr. Eva Rahman Kabir, Chairperson, DoP, Brac University, and Dr. Shahana Sharmin, Advisor of BUPS. The distinguished speaker of the webinar was Dr. Abir Absar, Director, Global Regulatory Affairs, AstraZeneca. He currently advises the drug development team on the regulatory strategy for respiratory biologic products. Dr. Absar has extensive experience of working at USFDA as a clinical pharmacology reviewer. Having the relevant expertise and experience in this field, Dr. Absar introduced to the attendees what regulatory strategy is and gave them an insight into the biologic/biosimilar development process from a regulatory strategy perspective. He spoke about the prospect of regulatory strategy as a career within the pharmaceutical industry and provided valuable advice to aspiring students on how to develop the necessary skill set to pursue this career path. By sharing his own academic and professional journey, Dr. Absar encouraged students to utilize their knowledge of pharmaceutical sciences to aim for leadership roles in various streams within the pharmaceutical sector. Dr. Absar also discussed real-world case studies on biosimilar and biologic products and explained in-depth the regulatory pathways involved in their development and approval. The webinar was very informative and interactive. The attendees asked excellent questions which reflected their enthusiasm towards building a career as a regulatory strategist.

The two-hour long webinar was moderated by Ms. Namara Mariam Chowdhury, Lecturer at the Department of Pharmacy, Brac University. The overall technical part of the event was taken care of by Mr. Faruque Azam, and Ms. Tanisha Momtaz, lecturers of the Department of Pharmacy.

Written by: Department of Pharmacy

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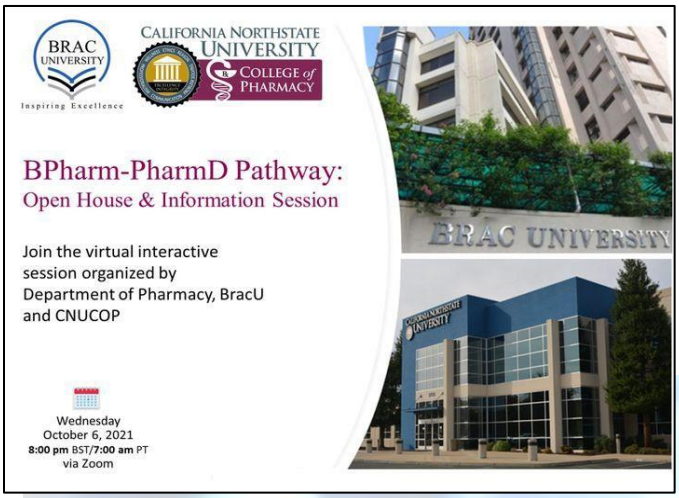
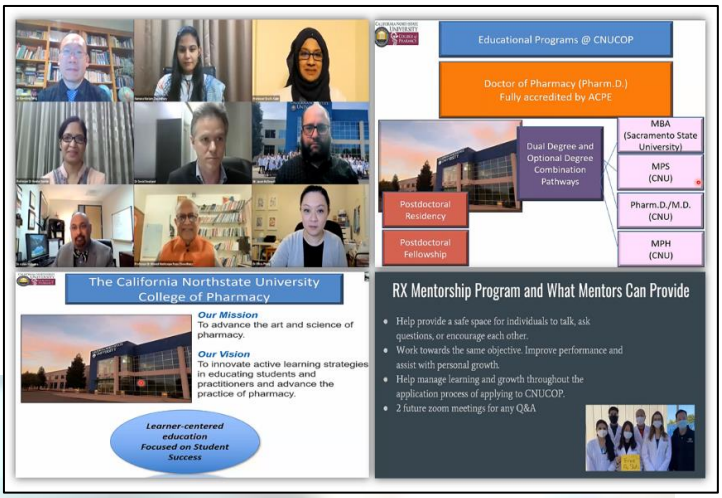
BPharm-PharmD Pathway: Open house and Information Session





A new BPharm - PharmD Pathway Program has been introduced in Bangladesh for the very first time by the Department of Pharmacy (DoP), Brac University. The department and California Northstate University, College of Pharmacy (CNUCOP) hosted a virtual Open House event on October 6, 2021 at 8:00pm (Bangladesh Standard Time) to introduce the new pathway program. The six year-long undergraduate degree will entail completing the first two years of study at DoP, Brac University and finishing the next four years at CNUCOP in the US. The session was held on Zoom for registered students, their guardians and alumni of the department and was live-streamed on the department's Facebook page.

The speakers at the event were Professor Dr. Eva Rahman Kabir, Chairperson, DoP, Brac University, Professor Dr. Hasina Yasmin, Deputy Chairperson, DoP, Brac University, Professor Dr. Sultan Hafeez Rahman, Member, Board of Trustees, Brac University, Dr. David Dowland, Registrar, Brac University, Professor Dr. Ahmed Mushtaque Raza Chowdhury, Convenor, Bangladesh Education Watch and Bangladesh Health Watch and Former Vice-Chairperson, BRAC, and Professor Dr. Samia Huq, Dean of General Education and Professor of Anthropology at Brac University. The speakers from CNUCOP were Xiaodong Feng, PhD, PharmD, Dean of CNUCOP, Dr. Fakhrul Ahsan, Distinguished Professor, Dr. Ashim Malhotra, Assistant Dean of Accreditation and Program Development, and Dr. Olivia Phung, Assistant Dean of Student Affairs. Esteemed guests from pharmaceutical companies and research institutes of Bangladesh also joined the online event.

The welcome speech was given by Professor Dr. Eva Rahman Kabir. She informed the students about the growing interest in pharmacy practice and the need for more patient-care oriented pharmacists and hospital based pharmacists in Bangladesh. Keeping this future prospect in mind, she was intent on providing the students with the opportunity to pursue PharmD as a professional degree. Professor Dr. Hasina Yasmin emphasized on the benefits of this pathway program for the students. The students were also introduced to CNUCOP in the US.

The speakers of CNUCOP discussed in detail about the profession of pharmacy in the United States and also gave an overview of the admissions process at CNUCOP. They also explained the Rx Mentoring Program of CNUCOP and how the students could benefit from it. Professor Dr. Fakhrul Ahsan shared his personal and professional experiences. The students' queries about the pathway program were addressed by the panelists.

The two-hour long virtual program was moderated by Ms. Namara Mariam Chowdhury, Lecturer at the Department of Pharmacy, Brac University, and the overall technical part of the event was taken care of by Mr. Easin Uddin Syed, Mr. Faruque Azam, and Ms. Tanisha Momtaz, lecturers of the Department of Pharmacy.

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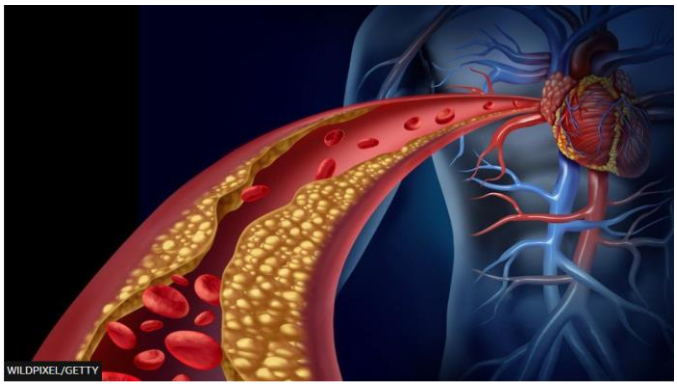
New Guidelines in Cholesterol Management: A Significant Shift in Cholesterol Management



On November 10, 2018 the American Heart Association (AHA) and the American College of Cardiology (ACC) released a new cholesterol guideline that includes, among other things, recommendations for more personalized risk assessments and new cholesterol-lowering drug options for people at the highest risk for cardiovascular disease (CVD). The guideline, which nearly a dozen other health care groups have approved, was simultaneously published in the AHA's journal Circulation and the Journal of the American College of Cardiology. The updated guidelines reinforce the importance of healthy living, lifestyle modification and prevention. They build on the major shift we made in our 2013 cholesterol recommendations to focus on identifying and addressing lifetime risks for cardiovascular disease. Having high cholesterol at any age increases that risk significantly. About one in three adults in the United States have high levels of LDL cholesterol, which contributes to fatty plaque buildups and narrowing of the arteries. High cholesterol treatment is not one-size-fits-all, and this guideline strongly establishes the importance of personalized care. Furthermore, the 2018 and 2019 guidelines from the American College of Cardiology and American Heart Association reflect the complexity of individualized cholesterol management. The documents address more detailed risk assessment, newer non-statin cholesterol-lowering drugs, special attention to patient subgroups, and consideration of the value of therapy, all with the aim of creating personalized treatment plans for each patient.
The new guidelines have updated patient risk assessment and treatment options in primary and secondary prevention. In primary prevention, the guidelines provide clarity regarding decision-making in patients at intermediate risk of atherosclerotic cardiovascular disease ("intermediate" meaning a 7.5%–20% 10-year risk).
In secondary prevention, the guidelines group patients according to their risk (high risk vs very high risk) and incorporate new non-statin therapies as add-on, evidence-based treatment options when low-density lipoprotein (LDL-C) remains above the 70 mg/dL threshold. The guidelines also discuss the cost and value of each treatment option for each treatment group.
The guidelines award classes of recommendations, signifying the certainty of benefit compared with the estimated risk and the strength of the recommendation.

- Class I (strong)—benefit greatly exceeds risk; treatment is recommended
- Class IIa (moderate)—benefit exceeds risk; treatment is reasonable
- Class IIb (weak)—benefit equals or exceeds risk; treatment might be reasonable
- Class III: No benefit (moderate)—benefit equals risk; treatment is not recommended
- Class III: Harm (strong)—risk exceeds benefit.

The guidelines also award levels of evidence to their recommendations:

- Level A—high-quality evidence
- Level B-R—moderate-quality evidence from randomized controlled trials
- Level B-NR—moderate quality evidence from nonrandomized trials
- Level C-LD—limited data
- Level C-EO—expert opinion

The new guidelines advocate a multifaceted approach to primary prevention of atherosclerotic cardiovascular disease through cholesterol management. As the risk due to high cholesterol levels is cumulative over the life span, the guidelines encourage lifestyle therapy for primary prevention at all ages and in all patient categories. Additionally, they outline decision algorithms to create a therapy that suits the individual needs of each patient.

References:
Khera, A. (2019). The New 2018 Cholesterol Guidelines: Filling Gaps and Expanding Opportunities. *Circulation*, *139*(25), 2805–2808. https://doi.org/10.1161/CIRCULATIONAHA.118.038629
Reiter-Brennan, C., Osei, A. D., Uddin, S. M. I., Orimoloye, O. A., Obisesan, O. H., Mirbolouk, M., Blaha, M. J., & Dzaye, O. (2020, April 1). *ACC/AHA*

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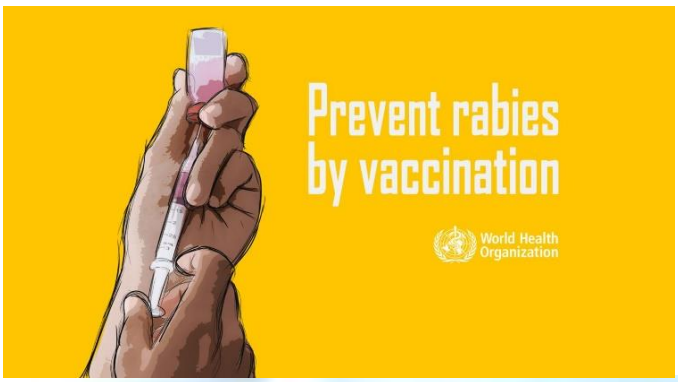
Rabies Immunization: Recommendations by WHO



Rabies is a neglected zoonotic disease responsible for an estimated 59,000 human deaths annually. Rural populations in Africa and Asia are predominantly affected, and approximately 40% of cases occur in children under the age of 15 years. Transmitted through bites and scratches from infected animals, dogs are responsible for up to 99% of human rabies cases. Although fatal once clinical signs appear, rabies is preventable through: mass dog vaccination to control disease at its source; awareness of rabies and the need to seek treatment if exposed; timely post-exposure prophylaxis (PEP) for people potentially exposed to rabies; and pre-exposure prophylaxis (PrEP) for those at high risk of rabies virus exposure.

The Strategic Advisory Group of Experts on Immunization (SAGE) established a Working Group (WG) on rabies vaccines and immunoglobulins in 2017 to undertake a comprehensive review of evidence and to propose revisions to SAGE on recommended rabies prophylaxis. This represents the first set of rabies immunization recommendations developed through the systematic working group process and replaces the 2010 recommendations. The 2018 update of the WHO position on rabies vaccines responds to the need for more programmatically feasible recommendations that aim to improve public health outcomes for rabies while maintaining the highest level of individual efficacy. By addressing the discrepancy between previous WHO recommendations and current practices of PEP and PrEP usage in endemic areas, the update aims to consider the most recent evidence available to improve access to life-saving care for vulnerable populations. This includes a focus on improving delivery of rabies PEP to better meet the needs of underserved populations through shorter, less costly and more feasible PEP and PrEP protocols, and for prudent use of RIG, without compromising effectiveness. The revised WHO position complements other, parallel efforts to provide clear and practical guidance for rabies prevention, such as the 3rd WHO Expert Consultation on Rabies, the ongoing updates to the WHO diagnostic manual on Laboratory Techniques in Rabies, and the Global Strategic Plan to End Human Deaths from Dog-Mediated Rabies by 2030. Factors that are taken into consideration when making recommendations include: disease epidemiology and clinical profile; the benefits and harms of the options; values pertaining to the importance of the desirable and undesirable effects; equity considerations; feasibility and resource implications including economic considerations; social values and preferences, and acceptability; Health-system opportunities, and interaction with other existing intervention and control strategies. Overall, the revised recommendations will make rabies vaccine schedules more efficient by allowing for the use of shorter, cost and dose saving ID regimens, and reducing the need for RIG. The challenge is now for countries and communities to implement these changes to improve access to life-saving PEP and reduce the burden of this fatal disease. Adopting the new regimens, including switching from IM to ID vaccination is key to increasing affordability, ease, and access to rabies PEP and PrEP. Vaccine manufacturers are strongly encouraged to submit a license variation application to national regulatory authorities for inclusion of ID administration and WHO recommended schedules as approved use on the label.

Further, the development, licensure, and use of mAb products as an alternative to eRIG or hRIG is encouraged, as mAbs can be produced with standardized quality in large quantities, do not use animals in the production process, and have higher effectiveness and reduced risk of adverse events. The development of products containing two or more mAbs with non-overlapping epitopes would be useful. Additionally, the WHO recommends that a registry be maintained to monitor the post-licensure effectiveness of mAb products.

The 2018 update of the WHO position on rabies immunization is an important step towards improving public health outcomes for rabies, increasing health equity and ultimately reaching the global goal of zero human rabies deaths by 2030, worldwide.

References:
O'Brien, K. L., & Nolan, T. (2019). The WHO position on rabies immunization – 2018 updates. *Vaccine, 37*, A85–A87. https://doi.org/10.1016/J.VACCINE.2018.10.014

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