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Objectives of SEARPharm Forum

A Forum of FIP & WHO with National Pharmaceutical Association of the South East Asian Region (SEAR) with objective to encourage and support a dialogue and collaboration among national and regional pharmaceutical associations in the South-East Asia region of WHO and WHO SEARO. Bangladesh, India, Indonesia, Sri Lanka and Thailand are the founding nations of SEAR Pharm Forum, while Bhutan, DPR Korea, Maldives, Myanmar, Nepal and Timor-Leste are invited members of the forum. The defined objectives are,

• Improving health in the South-East Asian region by development and enhancement of pharmacy practice (Good Pharmacy Practice).
• Encouraging the implementation of pharmacy service and pharmacy practice projects by national pharmaceutical associations.
• Supporting WHO-policies and goals.
• Integrating appropriate WHO policies into undergraduate, postgraduate, and continuing education programmes in pharmacy.
• Formulating policy statements on health issues.
• Combating the production and distribution of counterfeit medicine and sale of medicine by people who are not qualified.

About *i*-CARE Bulletin: The objective of *i*-CARE Bulletin (a quarterly publishing e-news bulletin) is to disseminate the new knowledge and practices evolved to curtail antimicrobial resistance (AMR) and will address the issues in primary health care support, medication errors, rational use of medicine, case studies, utilization of skills of pharmacists, use of off label drugs and legislation, disposables and medical devices and internet pharmacies.

The *i*-CARE Bulletin structure is designed with primary focus on insights on antimicrobial resistance and health care activities of various organizations in SEA region, news related to initiatives of WHO, FIP, Common wealth association, SEARPharm Forum and its members /pharmaceutical associations. *i*-CARE Bulletin accepts, in English, review articles, articles for educational forum, short communications), letter to editor, case reports and interesting fillers. Articles concerning all aspects of antimicrobial resistance will be considered.

**Manuscript Submission procedure:** Authors should keep their manuscripts as short as possible. Manuscript should be typed, double-spaced with 1" margins on all sides. The manuscript shall be prepared in Times New Roman font using a font size of 12. Title shall be in a font size 14. The pages shall be numbered consecutively with arabic numbers. The language of manuscript must be simple and explicit in English.

**Review Articles and Educational Forum:** The authors should review the recent trends or advances in that field in the light of their own work. These articles should contain a covering letter, title page, summary and key words.

**Short Communications and Correspondence:** This small research communication or a commentary, should contain a covering letter, title page, summary (need not be structured) and key words. They should be in a way of IMRaD format.

**References:** References are to be cited in the text by superscribed number and should be in the order in which they appear. The number of references should normally be restricted to a maximum of 20. Majority of them should preferably be of articles published in the last 10 years. The references must be verified by the author(s) against the original documents. The list of references should be typed double spaced in the Vancouver style. All the references, figures and tables in the text shall be numbered consecutively as they first appear.

All submissions shall be forwarded as email attachment to icaresear@gmail.com
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Dear Readers,

“In the fight against COVID-19, our shield is the healthcare system and our soldiers, healthcare professionals, which undoubtedly include pharmacists - Authentic heroes and frontline health workers”

In an era of rapid change in health care delivery, the pharmacy profession is experiencing significant growth and development. Traditionally, pharmacy was regarded as a transitional discipline between the health and chemical sciences and as a profession charged with ensuring the safe use of medication. The mid 90’s observed a gradual expansion shift of their roles, duties and responsibilities, from essentially products-based, to services-based, and patient-centered.

In December 2019, an alarming epidemic of unexplained etiology occurred in Wuhan City, China. The World Health Organization (WHO) described the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as the infective agent, causing the coronavirus disease 2019 (COVID-19), and classified it as a pandemic on March 11, 2020.

Pharmacists role across the globe broadened from routine duties to preventive activities such as disease monitoring and surveillance, immunizations, and diagnostic testing. Pharmacists helped the outbreak by promoting infection control measures and educating the public on how to avoid the disease spread. Pharmaceutical care, medication therapy, infection control, and vaccination are among the high priority role delivered by the pharmacists during this epidemic.

In the fight against COVID-19, our shield is the healthcare system and our soldiers, healthcare professionals, which undoubtedly include pharmacists. Pharmacists have not stopped working because of COVID-19 and in fact, have stepped up to take on more responsibilities at community, hospital, industrial, drug regulatory and administrative level. The post-COVID-19 post-pharmaceutical care era has begun and unearthed new opportunities in pharmacy profession and practice, to face crises and public health emergencies and mitigate the devastating outcomes.

T.V. Narayana
President
SEARPharm Forum
Dear Readers,

While the globe engage the pandemic of novel corona virus disease 2019 (COVID-19), described as both a wake-up call and a dress rehearsal for future challenges. It remains vital for our health care system to continue caring for all patients while mitigating their exposure to potential sources of infection and educating the public on how to avoid the disease spread.

We read, with great appreciation, the President’s message “In the fight against COVID-19, our shield is the healthcare system and our soldiers, healthcare professionals, which undoubtedly include pharmacists-Authentic heroes and frontline health workers” highlighting multilevel-engagements of pharmacists during the COVID-19 Pandemic.

We would like to add that our embrace of N95 Masks, press priorities of automatic production units and regulatory perspectives. order to avoid contamination due to human intervention.

In addition, this issue also highlights the current challenges regarding antimicrobial resistance in dental care; importance of the Commonwealth Partnerships for Antimicrobial Stewardship (CwPAMS) programme, and the report of FIP’s Programme on Transforming Vaccination Globally and Regionally convened between September to December 2020 which recaps the primary outcomes of the 24-event digital series.

We appreciate and would like to take this moment to thank all of you on the front lines of fighting the pandemic, and caring for people affected by it.

Best Regards,

Dr P Ramalingam
Editor

Dr Mohanraj M Rathinavelu
Dr G Sumalatha
Associate Editors
N95 Masks: Advantages, need of automatic production units and regulatory perspectives

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Abstract:
The global outbreak of COVID-19 has posed one of the greatest challenges to both lives and livelihoods. Countries affected by this pandemic have adopted different approaches like hand hygiene, social distancing, quarantines, limitations to travel and large gatherings etc., and use of masks is one of them. With respect to this, different types of masks are available like surgical and N95 respirators, N95 being more efficient as compared to other face masks. Safe and quality production of these masks is yet another challenge faced by India as the country is not a major producer of Personal Protective Equipment’s. This article thus summarizes about the different types of masks and the need of automatic masks production units in order to avoid contamination due to human intervention. In addition, this article also highlights the importance of regulating the production of mask by Indian Regulatory Authorities as regulated by US FDA.

Background:
The Coronavirus disease, COVID-19, now declared a pandemic by the World Health Organization (WHO), came to light on December 31, 2019 when China observed cluster-cases of pneumonia (unknown cause) in Wuhan City in Hubei Province. This virus is mainly transmitted through the droplets generated when an infected person coughs, sneezes, or exhales. Thus, the risk of infection is increased on coming in close contact with the infected person or by touching a contaminated surface and subsequently the eyes, nose or mouth. As a result, the use of a mask has become indispensable in the current scenario. A mask, per se, is a covering, made of fiber or gauze which is intended to fit over the nose and mouth in order to protect against air pollutants or infection of the wearer or of the patient if used during a surgery.

The use of mask in the present circumstances can be understood when on March 27, 2020 George Gao, Director, Chinese Centre for Disease Control and Prevention, said in an interview to Science that the United States and Europe made “a big mistake” by not wearing masks. “Droplets play a very important role - you’ve got to wear a mask, because when you speak, there are always droplets coming out of your mouth. Many people have asymptomatic or pre-symptomatic infections. If they are wearing face masks, it can prevent droplets that carry the virus from escaping and infecting others.”

Types of masks:
There are different types of masks available but not all serve the same purpose. N95 respirators and surgical masks are examples of personal protective equipment that are used to protect the wearer from airborne particles and from liquid contaminating the face. The major difference between a N95 respirator and a surgical mask is the intended use. According to WHO,¹ medical masks are defined as surgical or procedure masks that are flat or pleated (some are shaped like cups); they are affixed to the head with straps. They are tested according to a set of standardized test methods (ASTM F2100, EN 14683, or equivalent) that aim to balance high filtration, adequate breath ability and optionally, fluid penetration resistance. Though wearing a medical mask is one of the prevention measures, the use of a mask alone is insufficient to provide an adequate level of protection, if other measures like hand hygiene are not adopted. Surgical masks are made in different thicknesses and with different protection ability which is regulated under FDA 21 CFR 878.4040². If worn properly, a surgical mask can block large-particle droplets, sprays, or splatter that may contain viruses and bacteria, from reaching the mouth and nose. Surgical masks may also help to reduce exposure of saliva and respiratory secretions to others.
Other type of mask called the N95 respirators are meant to reduce respiratory exposure to airborne contaminants of the wearer. ‘CE’ marked respirators are tested, certified and approved to a recognized standard. They are marked with the standard (e.g. EN 149:2001 in the EU or N95 in the US) and an additional code such as FFP2 (medium efficiency) or FFP3 (high efficiency) (FFP = Filtering Face Piece) is shown on EU respirators. The US N95 standard is roughly equivalent to FFP2 or 3 as it is efficient up to 10 x the local occupational exposure limit (OEL)\(^3\). The FFP number is directly proportional to the protection ability of the respirator if used properly. Some of these disposable respirators contain exhaling valves that are more comfortable to wear. Also, it is important to note that N95 respirators with exhalation valves should not be used when sterile conditions are needed.

**Regulatory perspectives**

The 'N95' designation means that when subjected to careful testing, the respirator blocks at least 95 percent of very small (0.3 micron) test particles. If properly fitted, the filtration capabilities of N95 respirators exceed those of face masks. Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA) regulate N95 respirators. The N95 respirator can make it more difficult for the wearer to breathe thus people with medical conditions that causes difficulty inbreathing should check with their health care provider before using an N95 respirator. The surgical N95 respirators are class II devices regulated by the FDA, under 21 CFR 878.4040, and CDC NIOSH under 42 CFR Part 84. The FDA has a Memorandum of Understanding (MOU) with CDC NIOSH which outlines the framework for coordination and collaboration between the FDA and NIOSH for regulation of this subset of N95 respirators\(^3\). The CDC does not recommend the use of N95 respirators in general public wear to protect themselves from COVID-19 as these critical supplies must be reserved for health care workers working in the frontline to combat COVID-19. As false sense of security, leading to potentially less adherence to other preventive measures viz physical distancing and hand hygiene is growing in the general public, India is observing a diversion of mask supplies and consequent shortage of mask for health care workers and those in need. This demands for an urgent, rapid and safe production of these mask.

**Mask Production: “Zero Touch” Technique**

The CDC has also recommended and emphasized the practice of using ‘face coverings’, not necessarily ‘face masks’. The basic difference between them is that a face covering can be any cloth that covers the nose and mouth whereas a facemask is more fitted, has specific shape that covers nose and mouth via ear straps. The plausible reason of this encouragement is the shortage of the surgical and N95 respiratory masks in hospitals and at various testing centers. The effectiveness of a face covering in comparison to the face mask has not been put to test however, a homemade face covering was suggested to be an option used by a healthy person instead of a mask produced in a compromised environment; taking into consideration the larger interest and till the time there is enough production of ‘healthy masks’ (produced with minimum human touch to eliminate the possibility of contamination during the production process).

The advent of Covid-19 has forced the use of various kinds of masks on a daily basis. India was never a major producer of the safety equipment's including the masks and the same were imported from other countries like China at a cheaper rate. However, due to the said virus, the imports have been restricted and the country has been obligated to make home productions of the safety equipment's including the masks.
As it has been established that a person can possibly get COVID-19 by touching a surface or an object that has the virus on it and then touching his own mouth, nose, or eyes, the risk of contamination and human to human transfer is highest in the factory outlets where safety precautions are not taken into consideration. Consequently, the sharp rise in demand along with the lack of regulations governing the masks production process/premises, has enabled the manufactures to mass produce faulty and contaminated masks keeping the health of the people at stake.

Under such conditions it is imperative that the masks while production has no or limited human contact and the same are prepared via automatic production machine if possible. Further, the automatic mask making machine works at a higher speed thus increasing the productivity and at the same time produce very high-quality types masks owing to higher quality predictability. Also, improvement in robustness/consistency of the mask making process using the machine can be seen. With the automatic mask production, the amount of money spent in the production process by hiring labour resources will be highly reduced. Due to consistency and high level of accuracy, there is very little wastage of raw materials thus reducing production cost. Since the machine does not require a lot of human labour assistance, there will be less danger of contamination of masks or other people and apart from that, the machine has automatic sensors that will shut it down in the case of danger or malfunctions. Nonetheless, using an automatic machine, high level of accuracy in determining quality and size beyond the human capabilities will be met.

Figure: Comparison of structural composition of
(a) Surgical masks (3 layers) and
(b) N95 masks (6 layers)
**Conclusion:**
Where surgical masks are loose-fitting physical barriers, N95 respirators are designed to achieve a very close facial fit and very efficient filtration of airborne particles. Besides, the edges of the surgical masks do not form a seal around the nose and mouth but the edges of the N95 respirators are sealed and secured which gives an upper hand to the use of N95. But, for the mass production of these masks, risk-benefit analysis is much needed. Though for the automatic masks production, the machine cost is significantly high as compared to the hand-driven machine but considering the contamination by human interventions, automatic masks production is the only viable option left and is proposed to be included in set of regulations in India similar to US FDA Medical Devices in order to ensure safety of public at large.

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Antimicrobial Resistance in Dental Care—Current Challenges (Part II)

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In the first part of our article-series we discussed the fundamentals of Antimicrobial resistance (AMR) in dentistry.1 In this part we will further discuss the other key aspects of AMR in oral micro-flora and strategies for curbing AMR. (i-CARE Bulletin, 2020, Vol 1, Iss 2, Pg. No. 41-42).

Penicillin and metronidazole are the most commonly prescribed antimicrobial agents (AMA) by the dentists.2-4 These AMA are capable of inducing AMR in oral microflora.2 One of the first evidence of AMR in oral microflora was discovered in 1986, when streptococci producing beta-lactamase were isolated from the sub-gingival plaque of adults with periodontitis.5 Several studies that followed, found varying degrees of AMR in oral microflora to penicillin.6-7 However the bigger cause for concern is the detection of interspecies transfer of resistance determinants occurring between streptococcus pneumonia and other α-hemolytic streptococci.6 A Spanish study conducted in 2002, found isolates of Porphyromonas Gingivalis strains capable of producing β-lactamase from periodontal pockets.8 Studies have also revealed strong evidence of AMR in several anaerobic oral microbes such as Prevotella, Fusobacterium and Veillonella.9

Dentists frequently tend to use metronidazole, empirically in combination with one or more antibiotics such as amoxicillin to target both aerobic and anaerobic microorganisms. Unfortunately, this has led to a rapid emergence of AMR to metronidazole. Researchers state that the AMR (to metronidazole) would have developed at a slower pace if metronidazole's were to be used alone.2 Evidence AMR to metronidazole have been observed in several species of oral microflora such as Lactobacillus, Actinomyces Israelii, Prevotella and Actinobacillus Actinomycetemcomitans.2

Evidence of AMR to cephalosporins, metronidazole, tetracyclines and macrolide antibiotics have also emerged over the years.2 There is a growing evidence of literature suggesting that several frontline antibiotics have developed AMR not just in the pathogenic organisms but also to oral microflora necessitating swift action from the health care community.

International dental bodies such as Fédération Dentaire Internationale (FDI) have devised strategies in line with the WHO strategies to tackle the problem of AMR.10 The strategies focus on factors such as improving awareness of AMR, supporting AMR surveillance, AMR research, optimizing use of AMA, reducing incidence of infection by vaccinations, early diagnosis and other interventions.10 It has been stated that raising awareness in specific interest groups (health care providers) is very important in the initial stage of creating awareness as it aids in channeling inadequate resources to achieve specific objectives for raising awareness. This step can be very crucial, as it improves the likelihood of behavioral change. It has been suggested The general public can be targeted at an advanced stage with definite strategies.11 A dependable surveillance of current status and future predictions of AMR is indispensable to tackle the global drug-resistant crisis.12 AMR surveillance helps us to determine several important factors such as the magnitude of the problem, increase or decrease in incidence rates.
of AMR, emergence of new types of AMR and association particular type AMR with a specific outbreak.\textsuperscript{13} There has been a major focus on research in the management of AMR. Various novel agents such as antimicrobial polymers, polymer-based antimicrobial hydrogels and polymer-coated antimicrobial surfaces have been developed over the recent years.\textsuperscript{14}

Majority of the studies on AMR are based on the evaluation of resistance to industrially produced antimicrobials used in medical treatment. It is very important to carry out research on microorganisms that produce antimicrobial compounds and understand the mechanism of AMR. It equally important to better our understanding the infections, from micro-molecular level to epidemiological level and keep surveillance of the disease trends. Heavy emphasis should be laid on prevention techniques and vaccine development and reinforce the old saying “prevention is better than cure”.

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9. FDI continues to represent the profession at global event on antimicrobial resistance (available at https://www.fdiworlddental.org/news/20171117/fdi-continues-to-represent-the-profession-at-global-event-on-antimicrobial-resistance)
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The Commonwealth Partnerships for Antimicrobial Stewardship

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Antimicrobial Resistance (AMR) is a global health problem affecting the delivery of safe, effective healthcare in all settings and all countries. The ability of microorganisms to become resistant to the effect of antimicrobials is an inevitable evolutionary process, however misuse and over-use of antimicrobial agents exacerbates and accelerates the development of resistance. Addressing the rising threat of AMR requires a global holistic and multisectoral approach, often referred to as ‘One Health’.

Over the last year, a pharmacy-led health partnerships approach has been employed to connect multidisciplinary health workers and academics in the UK with colleagues in Ghana, Uganda, Tanzania and Zambia to collaboratively develop antimicrobial stewardship (AMS) interventions and build training capacity to tackle AMR.

The Commonwealth Partnerships for Antimicrobial Stewardship (CwPAMS) programme aimed to increase the rational use of antibiotics, and therefore reduce morbidity and mortality associated with AMR. As part of the programme, UK staff volunteered time and expertise to co-develop projects, resulting in 1500 healthcare workers becoming trained in AMS, 253 of whom were pharmacists (Figure 1). The programme resulted in the creation of a Toolkit of resources from the partnerships to complement guidance provided by the WHO AMS Practical Toolkit.¹ In addition, the first cohort of Global Health Pharmacy Fellows completed a successful leadership year as part of the Chief Pharmaceutical Officer’s Global Health Fellowship.²

The CwPAMS programme has resulted in improved surveillance of antimicrobial prescribing data, through increased data collection in the included countries. Prior to the start of CwPAMS, only one hospital had conducted data collection through the Global Point Prevalence Survey (GPPS), this has since increased to ten, across the four countries.

Many of the CwPAMS Partnerships collaboratively

Figure 1: The impact of the CwPAMS programme
The toolkit provides a platform to share the learning from the CwPAMS projects and the resources that were developed and outlines strategies that healthcare organisations could implement as part of an AMS workplan. The toolkit gives case examples of the CwPAMS projects and links to an online repository of resources used within the projects, such as AMS committee structures, terms of reference and work plans for committees, teaching slides for delivery of multi-disciplinary courses in AMS, audit templates, guideline templates and local quality improvement projects. The structure of developed training resources and ran multi-disciplinary training on AMS. One partnership co-developed a training course which was delivered on 12 occasions over a 3-week period, providing AMS training to 212 healthcare workers, including 97 nurses, 20 midwives, 18 medical officers and 16 pharmacists. After completing the course, all participants signed up and pledged to be antibiotic guardians, ensuring continued commitment to the fight against AMR.

The CwPAMS programme has led to the development of several resources, which have been collated into a toolkit, available from the Commonwealth Pharmacists Association (CPA).
the toolkit follows that of the seven core elements of AMS (Figure 2).

All resources within the toolkit are free to access and available for adaptation and use in any healthcare institute to support implementing the recommendations of AMS programmes in health-care facilities. The toolkit may be used by healthcare facilities to identify their own AMS priorities and implement a workplan on a local level.

During the COVID19 pandemic, CwPAMS has both prepared and continued to support healthcare institutions in their infection prevention and control processes. Partnerships were able to pivot work to include initiatives such as training on production of alcohol-based hand sanitiser – a bidirectional learning experience for both overseas and UK practitioners.5

The Commonwealth Partnerships for Antimicrobial Stewardship (CwPAMS) Programme is funded by UK Aid’s Fleming Fund* and managed by the Commonwealth Pharmacists Association and the Tropical Health Education Trust (THET).8

References:


* The Fleming Fund is a £265 million UK aid investment to tackle antimicrobial resistance by supporting low- and middle-income countries to generate, use and share data on AMR. The programme is managed by the UK Department of Health and Social Care. The views expressed in this publication are those of the author and not necessarily those of the Department of Health and Social Care.
**News & Announcements**

*Source: https://www.who.int/southeastasia/news/releases*

COVID-19 reignites drive for a “One Health” approach to tackle preventable illnesses at the animal-human-ecosystems interface:

**Stronger Together: FAO, OIE and WHO commit to joint multi-sectoral efforts in Asia and the Pacific**

As COVID-19 continues to inflict illness and misery across the Asia-Pacific region, three international organizations have vowed to collaborate and intensify their joint efforts to respond to all health threats, including zoonotic influenza, rabies, antimicrobial resistance and those affecting food safety, through a One Health approach.

The Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (OIE) and the World Health Organization (WHO) have reaffirmed their joint commitment to work with their Members through multi-sectoral coordination. A joint Statement of Intent to Coordinate was signed by Asia-Pacific representatives from the organisations in support of the Tripartite One Health Coordination Group.

The Regional Tripartite partners are committed to work with Members through multi-sectoral coordination efforts to support countries’ efforts to prevent and manage health threats and strengthen their coordinated efforts, with the aim of protecting the health of animals and people. The Tripartite One Health Coordination Group for Asia and the Pacific undertakes joint activities including regional workshops on multisectoral collaboration at the animal-human-ecosystems interface.

In October 2020, regional representatives from the Tripartite organisations signed a Statement of Intent to Coordinate. This statement acknowledges the importance of close coordination and communication across sectors, and commits to working together to partner with their Member States and regional organisations to strengthen coordinated efforts to fight existing and emerging health threats.

24 December 2020 New Delhi, India

**WHO and EU join together to support COVID-19 response and systems strengthening in Asia:**

The World Health Organization (WHO) and the European Union (EU) agreed to join forces to support eight South East Asian countries in their response to COVID-19 and to strengthen preparedness for future pandemics.

The EU is providing €20 million for a South East Asia pandemic response and preparedness programme. WHO will use the funds to continue supporting the governments of Cambodia, Indonesia, Lao People’s Democratic Republic, Malaysia, Myanmar, the Philippines, Thailand and Viet Nam.

“The European Union is one of WHO’s major partners, particularly in emergency response. This partnership will go a long way in ensuring that the South-East Asian Region builds back better during and after the COVID-19 pandemic and is stronger and more resilient in the years ahead,” said Dr Poonam Khetrapal Singh, WHO’s Regional Director for South-East Asia.

In line with the Global Strategic Preparedness and Response Plan and guided by the Asia Pacific strategy for emerging diseases and public health emergencies (APSED III), the programme aims to strengthen health systems and to support the COVID-19 response in the...
eight South East Asian countries, with a particular focus on reaching the unreached. The funds will be used to:
- Mobilize all sectors and communities to ensure participation in prevention, preparedness and response activities;
- Control sporadic cases, clusters and community transmission;
- Suppress community transmission; and
- Reduce deaths from COVID-19.

The programme represents a joint effort between the EU and WHO’s Regional Offices for South-East Asia (which includes Indonesia, Myanmar and Thailand) and the Western Pacific (which includes Cambodia, Lao People’s Democratic Republic, Malaysia, the Philippines and Viet Nam). To ensure that the interventions in each country will be in line with national priorities as outlined in the national response plans, each WHO Region is working closely with the governments of those countries and other stakeholders, including civil society organizations.

“These countries have spent more than a decade preparing for events with pandemic potential, by strengthening their health systems in anticipation of an event like the COVID-19 pandemic. This support from the EU will help to build on this work, so that countries across South East Asia are prepared for the next pandemic or health emergency event,” said Dr Takeshi Kasai, WHO’s Regional Director for the Western Pacific.

WHO, national regulators and vaccine manufacturers in South-East Asia Region discuss COVID-19 vaccines:

The World Health Organization, national regulatory authorities and vaccine manufacturers in WHO South-East Asia Region discussed fast tracking of COVID-19 vaccine rollout in Member countries.

“The vaccine manufacturing and regulatory sectors have a critical role to play in equitable and efficient deployment of vaccines,” said Dr Poonam Khetrapal Singh, Regional Director, WHO South-East Asia Region, at the two-day virtual meeting.

The meeting deliberated processes and timelines to fast-track registration of COVID-19 vaccines in countries using the Emergency Use Listing procedures while comprehending the landscape of COVID-19 vaccine production in the Region.

Aimed at strengthening collaboration between national programmes, vaccine producers and regulators in the region for COVID-19 vaccine deployment, the meeting provided a platform for interaction and experience sharing for vaccine registration, deployment and regulation.
News & Announcements

The Regional Director said all countries in the Region are now developing and finalizing national deployment and vaccination plans for COVID-19, of which regulatory preparedness is a core component. Establishing expedited regulatory pathways for vaccine approval and adjusting regulatory pathways to the type of vaccine that is developed and filed for approval remains critical as emergency use authorization will precede full licensure, Dr Khetrapal Singh said.

While vaccine licensure systems may need to be modified, having standard operating procedures and stipulated timelines for emergency use authorization would be vital, she said. The Regional Director emphasized on effective coordination, collaboration and information-sharing. From R&D to production, and from information on country readiness to post-marketing surveillance, manufacturers, regulators, policy-makers and planners must continue to work together to optimize and refine vaccine deployment.

“Countries in our Region are among the world’s largest vaccine manufacturers, and the vaccines produced here are likely to be administered to billions of people globally. I am certain that together, in solidarity with all people of the Region and world, you will effectively contribute to health and well-being of all,” Dr Khetrapal Singh said.

Key global and regional partners such as GAVI and UNICEF participated in the meeting. Among the vaccine manufacturers, from India Bharat Biotech International Ltd, Biological E Ltd, Cadila Healthcare Ltd, Serum Institute of India Pvt. Ltd, Dr Reddy’s Laboratories and Wockhardt Limited; from Indonesia Bio Farma Limited, and from Thailand Government Pharmaceutical Organization (GPO), Bionet Asia Co.Ltd and Siam Bioscience, participated in the meeting.

This was the second such meeting with vaccine manufacturers and regulators organized in WHO South East Asia Region, with the first held in April.

WHO has been supporting Member countries of the Region prepare for COVID-19 vaccines. A special session of the WHO South-East Asia Regional Immunization Technical Advisory Group was organized in November. The expert group made a series of recommendations including a fast tracking of the development of national deployment and vaccination plan, the application of guidelines provided by the ‘Values framework for the allocation and prioritization of COVID-19 vaccines’ and the ‘prioritization roadmap’ to identify priority populations and ensuring equity in delivery of COVID-19 vaccines, especially during the early stages when vaccine supply is expected to be limited.

The expert group also recommended that all countries should ensure availability of high-quality, complete and timely COVID-19 surveillance data on all risk groups, including migrants and remote or displaced populations, for decision-making related to vaccination. While establishing collaboration with other health programs and sectors for optimum delivery of vaccine, countries should also leverage their experience in vaccine delivery platforms for adults, including experience with seasonal and pandemic influenza vaccination and Measles and Rubella and Japanese Encephalitis vaccination campaigns, to find effective ways to reach eligible adults with COVID-19 vaccines.

Adjustments should be made to vaccination strategies in accordance with the COVID-19 prevention measures and plans developed for demand generation, community engagement and risk communication, with special consideration for overcoming vaccine hesitancy.
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Countries should leverage the use of existing networks, including those for polio, to support the deployment of COVID-19 vaccines where appropriate. The expert group highlighted the need for all countries to assess available cold chain space and meticulously plan cold chain requirement, including necessary improvements in storage, stock management, vaccine delivery strategy and waste management.

Earlier, WHO organized a meeting of cold chain managers of countries of the South-East Asia Region to help assess cold chain needs, identify gaps and plan for appropriate measures.

At the global level since April, the ACT-Accelerator partnership, launched by WHO and partners, has supported the fastest, most coordinated, and successful global effort in history to develop tools to fight COVID-19. Its vaccine pillar - COVAX - is co-led by WHO, Gavi and the Coalition for Epidemic Preparedness Innovations. It aims to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world.

11 December 2020 New Delhi

Reinvigorate response to HIV among challenges posed by pandemic: WHO

On World AIDS Day, WHO cautioned countries in South-East Asia Region against slow-down in services for HIV prevention, testing, and treatment, saying this could leave many vulnerable populations at greater risk of HIV infection and AIDS-related death. Addressing a virtual meeting of Ministers of Health and heads of National HIV programmes of Member States today, Dr Poonam Khetrapal Singh, the Regional Director of WHO South-East Asia Region said, ‘The theme for this year’s World AIDS Day, Global Solidarity – resilient services is very relevant. It’s a timely reminder that we must continue to work together and ensure that HIV services remain an integral part of our response to COVID-19. This year we must take stock of our response to HIV, learn from what has worked and accelerate those efforts to reach our goal of ending AIDS as a public health threat by 2030.’

Between 2010 and 2019, the Region has taken large strides in its response to HIV. Epidemiological trends show that both new infections and HIV-related deaths are continuing to decline, with the number of new HIV infections dropping by an estimated 23.8% and the number of AIDS-related deaths coming down by 26.7%. In 2019, an estimated 38 million people were living with HIV globally, of which 3.7 million were in the WHO South-East Asia Region.

However, Dr Khetrapal Singh pointed out that the rate of decline has plateaued over recent years and also that the region and across globe, we are lagging behind on 90-90-90 targets to be achieved by 2020. (These targets mean 90% of all people estimated to be living with HIV will know their HIV status, -90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy and 90% of all people receiving antiretroviral therapy will have viral suppression).

According to the UNAIDS 2020 Global AIDS Report, nearly 98% of new HIV infections in the Asia-Pacific Region are occurring among key and vulnerable populations. ‘Acting on the insights and advice of key populations is a precondition of success,’ said the Regional Director.

Further, the COVID-19 pandemic, which took a huge toll on essential health services, has
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also affected access to HIV prevention, testing, and treatment services. There is a clear and present danger of many vulnerable populations finding themselves at greater risk of HIV infection and AIDS-related death.

‘The COVID-19 pandemic has given us the opportunity to learn from adversities. The examples of differentiated service delivery (reaching out to people at facility nearer to them or outside of health facility), dispensing of drugs for 3 months (as against existing practice on monthly dispensation), tasking shifting (dispensation of drugs by nurse/community workers to stable patients) and use of e-medicine for consultation, virtual interactions have led to greater comfort levels among service providers and clients. This is a step towards strengthening HIV prevention, one that can help and re-invigorate our response to HIV,’ said Dr Khetrapal Singh at the high-level meeting.

Highlighting the role of community participation, she said, ‘We must harness the rich experience of communities affected by HIV. By empowering communities to prevent, detect and treat HIV, countries can make full use of a range of new tools such as pre-exposure prophylaxis and community-based and HIV self-testing, as well as better antiretroviral drugs such as Dolutegravir.’

At the virtual meeting, countries in the Region took the opportunity to share experiences and best practices on HIV service delivery amidst the pandemic, and the need to build even more resilient health systems to ensure rights-based HIV services continued to be available to people. Member States also outlined what was required to integrate HIV programmes within Universal Health Coverage.

‘As we stand at the last 10 year stretch of achieving the Sustainable Development Goals, our response to HIV in the Region remains critical and central to the goals of 2030,’ added Dr Khetrapal Singh.

1 December 2020 New Delhi

Polio networks bolster pandemic response in WHO South-East Asia Region:

Applying strategies from polio eradication programme, polio networks in WHO South-East Asia Region are helping strengthen core public health response measures to contain the COVID-19 pandemic.

“Within weeks of the COVID-19 outbreak, the integrated surveillance and immunization networks in five polio priority countries of the Region were re-purposed to support preparedness and response. Working among the most vulnerable population and areas, these networks are helping health authorities to detect, test, track, isolate and even prepare hospitals to provide adequate and timely treatment,” said Dr Poonam Khetrapal Singh, Regional Director WHO South-East Asia.

From assisting coordination at the national and sub-national levels, to training and building capacities for laboratory and other health workers for detecting cases, tracing contacts, and assessing public perceptions to hospital readiness and preparedness, the WHO’s polio surveillance networks in Bangladesh, India, Indonesia, Myanmar and Nepal, are supporting with strategies and initiatives, refined over the years and which helped the Region achieve polio-free certification in March 2014.

Using polio micro-plans, the surveillance medical officers’ team in India’s Uttar Pradesh state – the most populous state in the country – coordinated with the state government a massive initiative of house-to-house surveillance to identify people with symptoms of influenza-like illness and co-morbidities, covering 208 million people across all 75 districts in the state. The
exercise conducted twice in the last three months, helped identify over 100,000 people with symptoms each time, who were then followed up and tested for COVID-19, the Regional Director said citing one of the many examples of the polio network’s support in India. In Bangladesh, the polio surveillance network has trained 17,000 health workers and laboratory staff. It is also supporting training in infection prevention and control measures which will cover over 26,500 health workers across all districts and city corporations by month end. COVID-19 has been integrated into surveillance for vaccine preventable diseases in Indonesia, where all polio laboratories are now testing for COVID-19. In Myanmar, polio networks are providing critical operational support for timely shipping of COVID-19 samples from across the 17 states and regions to the National Health Laboratory in Yangon. In Nepal, the network facilitated resumption of routine immunization services, the first essential service to be restored during the lockdown. The country became the first in the Region to conduct a measles and rubella vaccination campaign during the pandemic, covering nearly 980,000 children up to the age of five years. Restoration of essential services is one of the key strategies of COVID-19 response to minimize the overall health impact of the pandemic. “These highly valuable resources continue to provide critical support to planning, operationalizing and even conducting key pandemic response initiatives, while also keep a strict vigil for the Region to remain polio-free,” Dr Khetrapal Singh said, lauding their efforts on the occasion of the World Polio Day observed on 24 October. In the coming months, our polio networks, with their vast knowledge on vaccination and tools and strategies tailored to reach the unreached and the most vulnerable, could play a critical role for COVID-19 vaccination roll out.

23 October 2020 New Delhi

Handwashing an effective tool to prevent COVID-19, other diseases:

Ten months into the pandemic, handwashing with soap remains one of our best defenses against the virus, along with other public health measures such as maintaining physical distance, avoiding crowded places, practising cough etiquette and wearing a mask wherever recommended. Global Handwashing Day observed annually on October 15 to raise awareness and highlight the importance of handwashing as an effective means of disease prevention – this year marks a critical reminder for the world and the Region that this simple, cost effective practice can save lives.

‘Handwashing has always been one of most effective ways of keeping diseases at bay. It is a simple act that pays in dividends when it comes to keeping ourselves healthy and safe. Handwashing is also one of the key cornerstones of COVID-19 prevention. Now more than ever as we embrace the new normal and live with COVID-19, hand hygiene needs to become an integral part of our daily routine and our lives, as we live through this pandemic, and beyond, to protect us from diseases,’ said Dr Poonam Khetrapal Singh, Regional Director, WHO South-East Asia Region.

With COVID-19 transmission mainly spreading between people through direct, indirect (through contaminated objects or surfaces), or close contact with infected people via mouth and nose secretions, washing hands with soap and running water is of critical importance. To
stop the spread of COVID-19, along with other COVID appropriate behaviours, the practice of handwashing at regular intervals is a must, after coughing or sneezing, when caring for the sick, after using the toilet, before eating, while preparing food and after handling animals or animal waste. Handwashing after touching common surfaces such as doorknobs or handles, or after one comes back home from visiting a public place will keep ourselves and others around us safe.

“Promoting hand hygiene at all levels of health care is also critical. Hand hygiene, a very simple action, is well accepted to be one of the primary modes of reducing health care-associated infection and of enhancing patient safety,” the Regional Director said.

The pandemic is still among us and it is far from over. We must remind ourselves of the basics that we as individuals can do to keep ourselves safe, she said.

This year’s Global Handwashing Day theme is Hand Hygiene for All and calls for all of society to achieve universal hand hygiene. To beat the virus today and ensure better health outcomes beyond the pandemic, handwashing with soap must be a priority now and in the future.

15 October 2020 New Delhi

**HAND HYGIENE FOR ALL**

October 15 is Global Handwashing Day, a global advocacy day dedicated to increasing awareness and understanding about the importance of handwashing with soap as an effective and affordable way to prevent diseases and save lives.

Global Handwashing Day is an opportunity to design, test, and replicate creative ways to encourage people to wash their hands with soap at critical times.

The COVID-19 pandemic provides a stark reminder that one of the most effective ways to stop the spread of a virus is also one of the simplest: hand hygiene, especially through handwashing with soap. To beat the virus today and ensure better health outcomes beyond the pandemic, handwashing with soap must be a priority now and in the future. This year’s theme, Hand Hygiene for All, calls for all of society to achieve universal hand hygiene.

No matter your role, you can celebrate Global Handwashing Day!
FIP’s Programme on Transforming Vaccination Globally and Regionally:

FIP’s Transforming Vaccination Globally and Regionally programme is a 3-series programme comprised of 24 events conducted between September and December 2020. The global virtual summit is a high-level event which recaps the primary outcomes of the 24-event digital series.

The main objective of the Series-1 was to identify the needs and considerations of the Pharmacist for transforming globally across practice, science and workforce. In series-1 schedule, 8 episodes were conducted which focused on identifying the needs for vaccine transformation through workforce enablement and addressing very important issues such as anti-science and vaccine hesitancy. Various moderators and the speakers across the globe shared their valuable views and insights for vaccination transformation. They also focused on the changes needed in workforce, professional practice, and pharmaceutical science to achieve global and regional transformation in vaccination delivery. They also highlighted the strategies to be followed for wide dissemination of vaccine information in the context of the pandemic in current vaccine delivery.

The Series-2 main objective was to discuss the mechanisms and drivers to progress the most relevant FIP Development Goals (FIPDGs) in the context of transforming vaccination in pharmacy. In series-2 schedule there were again 8 episodes that focused on the mechanisms and drivers for transformation of vaccination. FIPDGs and the agenda of improving vaccination worldwide came together in the Series-2 that outlined how pharmacists and pharmaceutical scientists will deliver on the promise of improved vaccination rates worldwide.

In the Series-3 schedule also there were 8 episodes, which concentrated on regional needs and drivers for transforming vaccination in various regions across the globe. In the first episode organized in the Europe region, the progress made in European Countries with regards the Quality and Universal access to vaccinations was discussed. The moderators and speakers of Series-3 also discussed the barriers and challenges and regional needs for future transformation of vaccination.

The episode 2 of Series 3 was, Regional needs and drivers for transformation vaccination: South East Asia. This event was moderated by Dr. G. Sumalatha, Executive Committee Member, SEARPharm Forum, India and Prof. Ashok Soni, Vice-President, FIP (UK). The speakers included, Dr. Rao Vadlamudi, Professional Secretary SEARPharm Forum and President, Commonwealth Pharmacist Association (India), Dr. Lalith Senarathna, Rajarata University, Sri Lanka, Dr. Kampanart Huanbutta, Assistant Dean, Faculty of Pharmacy, Burapha University, Thailand and Dr. Yagya Prasad Neupane, former chairman, Nepal Pharmacy Council, Nepal. The special guest of the episode was Dr Manisha Shridhar, Regional Advisor, WHO Regional Office for South-East Asia, India and Dr. Lina Bader, Lead for Workforce Transformation and Development, FIP was the facilitator. All speakers presented their views and insights to understand the South East Asian perspective in delivering the transformation of vaccination globally and regionally.
On December 15, 2020 in the Round Table Session, Dr. G. Sumalatha presented the outcome of the episode 2 of the Series-3 that dealt with regional needs and drivers for transforming vaccination in the South East Asia.

To sum up the situation in SEAR countries with reference to transforming vaccinations, Pharmacists are not authorized to vaccinate but involved only in store, maintain cold chain and supply vaccines against prescription in most countries. Advocacy is needed to ensure a legislation authorizing pharmacists to administer vaccines and under some circumstances to prescribe vaccines. Advocacy by the Indian Pharmaceutical Association and timely support by FIP resulted in a Government Notification listing pharmacist as vaccinators along with other healthcare workers. Authorized Pharmacists in SEAR countries need training to develop the required skills to become competent vaccinators. FIP to play a huge role to train and equip these Pharmacists to be competent vaccinators who can store, administer under proper advice, monitor safety and manage vaccine supply chain and waste disposal.

Dr. G. Sumalatha  
Associate Editor,  
i-CARE Bulletin.
Pharmacy profession around the world pledges to transform vaccination globally, regionally and locally

As part of a new FIP Commitment to Action on improving vaccination coverage through pharmacies, pharmacists, pharmacy technicians, pharmaceutical scientists and pharmacy educators around the world today pledged to transform vaccination globally, regionally and locally.

The commitment, launched today during the first FIP Virtual Global Summit on transforming vaccination in pharmacy, is the outcome of FIP’s “Transforming vaccination globally and regionally” digital programme, which began in September this year.

Among the 17 actions described in the commitment are to:

- Address vaccines hesitancy;
- Strive towards equity of access to vaccinations and with particular focus on expanding vaccination pathways for adults;
- Advocate for legislative frameworks that provide the regulatory assurance of pharmacist-delivered vaccination services and for appropriate funding models; and
- Ensure health system readiness for mass immunisation against current and future pandemics.

“Pharmacy is a highly skilled and trusted health workforce that can deliver an effective and impactful health intervention. All the actions in this commitment are urgently needed to ensure equitable access to vaccines and vaccination services to all people around the world, across all ages and leaving no-one behind, to reduce the burden of vaccine-preventable diseases, and so that pharmacists can play an even greater part in the fight against emerging diseases,” said FIP CEO Dr Catherine Duggan.

17 December 2020 FIP
The FIP Commitments to transforming vaccination globally and regionally:

1. Pharmacists, pharmaceutical scientists, and pharmacist academics will commit to improving healthcare outcomes with regards to access, equity, and quality by delivering the safest possible vaccines and vaccine-related services in the form that is most acceptable to healthcare consumers by all pharmacists in all settings.

2. Pharmacists will contribute to expanding vaccination pathways, especially for adults, in all countries, with the goal of increasing vaccination coverage globally, regionally and locally, in line with the FIP Development Goals.

3. Pharmacists and their organisations will strive towards equity of access to disease prevention interventions, including vaccinations, regardless of age, gender, income, location, ethnicity or other factors, leaving no-one behind.

4. Pharmacists will integrate the delivery of all vaccinations into their practice in all settings, in collaboration with health systems and authorities, other healthcare professions and education and training institutions.

5. Pharmacists, pharmaceutical academics, workforce planners and professional regulators will evolve undergraduate qualifications, workforce development, and professional regulations to ensure and maintain ongoing capacity (professionally and logistically) and competence by pharmacists in all settings to administer vaccines and provide vaccine-related services, ranging from supply to community education and awareness.

6. Pharmaceutical scientists will strive to improve vaccine uptake by developing vaccines that are efficacious, safe, practical to supply and deliver and acceptable to healthcare consumers.

7. Pharmacists and their organisations will advocate for legislative frameworks that provide the regulatory assurance of pharmacist-delivered vaccination services and define the conditions, criteria, and accountability for this activity as part of pharmacists’ scope of practice.

8. Pharmacist and organisations will contribute to building vaccine confidence by addressing vaccine hesitancy, concerns, misinformation and disinfection, ensuring that all people have access to reliable information and evidence-based advice about their safety, efficacy and value. Pharmacists will support ongoing antimicrobial stewardship by providing the highest level of vaccination for preventable diseases in all settings.

9. Pharmacists will collaborate with other health care providers to ensure the local workforce is best utilised to ensure maximum vaccination utilisation and coverage, while striving towards the autonomy of vaccination providers to deliver vaccines as per agreed protocols and criteria.

10. Pharmacists and their organisations will advocate for appropriate funding models for vaccines and vaccination services that ensure equity of access for all at the point of delivery across all vaccination providers.

11. FIP commits to increasing vaccination by empowering pharmacists in delivering vaccination services, strengthening undergraduate qualification in the area of pharmacist vaccination, addressing legislative and regulatory barriers to full pharmacist participation in vaccination delivery, and ensuring pharmacists have access to shared records that facilitate collaborative health care and vaccination service delivery.
In addition, pharmacists and member organisations will commit to drive previous FIP undertakings, including the FIP Call to action to expand the role of community pharmacies in vaccination, including the 7 action points:

1. Recognise and fully harness the potential and convenience of community pharmacies for public health, primary healthcare and disease prevention strategies, including vaccination.
2. Foster the full integration of community pharmacies in healthcare systems, by creating the regulatory and operational conditions for inter-professional collaboration, including access to shared patient health records and vaccination records.
3. Expand the regulatory scope of practice of appropriately trained and certified pharmacists to authorise them to administer a broad range of vaccines beyond infancy.
4. Promote the competence of pharmacists in vaccine administration through the development of the required knowledge and skills as an integral part of pharmacists’ foundational education and training, and/or through continuing professional development opportunities.
5. Invest in prevention strategies, including vaccines and vaccination services by all providers, including pharmacists, to ensure equity in access to vaccinations and the sustainability of the service.
6. Ensure health system readiness for mass immunisation against current and any future pandemics or other emerging diseases as soon as vaccines are available.

The above measures are urgently needed to ensure equitable access to vaccines and vaccination services to all people around the world, across all ages and leaving no-one behind, to reduce the burden of vaccine-preventable diseases, and so that pharmacists can play an even greater part in the fight against emerging diseases.

Jenelle Sobotka (USA) has been selected new chairperson for the FIP Foundation for Education and Research by the FIP Bureau.
Risk assessment for antibiotic resistance in South East Asia

SEAR's antibiotic challenge
Risks of emergence and spread of antibiotic resistance in South East Asia

The WHO South East Asia Region (SEAR) has unique characteristics that contribute to the likelihood of increasing resistance to antibiotics developing in the region. In their 2017 model published in The BMJ, Chereau and colleagues use a risk assessment approach to characterise the likelihood of emergence and spread of antibiotic resistance in the region. They conclude that the overall risk for emergence and spread of antibiotic resistance among humans in South East Asia is high.

Reference: Chereau Fanny, Opatowski Lulla, Toudjman Mathieu, Vong Sirenda. Risk assessment for antibiotic resistance in South East Asia BMJ 2017; 358 :j3393
World AIDS Day 2020
Global solidarity, resilient services

Let’s take a minute to thank everyone working to end AIDS

Protected and engaged health workers can deliver safe HIV services during COVID-19

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