

Pharmacy Ethics Related to the Covid-19 Pandemic Based on Core Ethical Principles Version 1.0

UNESCO CHAIR IN BIOETHICS

International Pharmacy Panel
Ethical Guidelines for Pharmacy

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In 2005, the United Nations, at its 33rd General Assembly, adopted a 26 article Universal Declaration of Bioethics and Human Rights. These principles coupled with the many discussions that have followed provide a pragmatic lens through which to view the present SARS-COVID-19 global pandemic [See <https://unesdoc.unesco.org/ark:/48223/pf0000142825.page=80> for full text of this Declaration].

As the world experiences a global pandemic of the novel Covid-19, and given the absence of a viable vaccine nor effective and safe treatment of patients having been infected with the novel virus, the international leaders of the profession of pharmacy are gathered to present these guidelines to the pharmacy practitioner community. Once a vaccine becomes available and when medicines are approved for treatment of COVID-19, these guidelines may require some modification.

The guidelines intended to provide the necessary guidance to pharmacy practitioners as they apply their knowledge, skills and clinical experience to the care of patients and colleagues in other professions in different parts of the world. Furthermore, in order to assure the most effective and safe caring of patients with whom pharmacists interact, that these guidelines can assure fundamental principles of ethical behavior and practice. [Based on Stephenson, LA et al., 2012]

Based on Core Ethical Principles we must consider the following:

1. Nonmaleficence—intent that actions undertaken will be done without harm

The assurance of *efficacy* and *safety* of vaccines, biologicals, medicines and contrast media serves as the underlying requirement for authorized use of these agents. Meeting the requirements under these two themes is the necessary element of assuring least harm. It must be understood however, that the use of all medicinal agents carries some element of risk. Mitigating that risk on behalf of the patient, under the principle of ‘do no harm’ is a key responsibility of the pharmacist. The latter is particularly important when medicines are used within an ‘off-label’, ‘experimental’ and ‘compassionate use’ protocol.

2. Autonomy—respect for independence of thought, intention, and action

Pharmacist must recognize that the patient is an autonomous decision-maker about their use of vaccines, biological agents, medicines and contrast media. The patient holds the ultimate decision regarding their willingness to be vaccinated and/or engage in a treatment modality that is based on medicinal agents. Notwithstanding that autonomy, public health priorities and goals must be made clear to the patient in order to preserve the health of the community. Furthermore, there may be occasions where the patient is unresponsive and under the supervision of a caregiver. In these latter circumstances, respectful application of patient desires is paramount in both receiving or declining treatment.

3. Justice—awareness that burdens and benefits must be distributed equally and equitably

Equality and equity in all aspects of the medication use process, from prescribing to ultimate use must be performed in a way that assures equal treatment to all. Moreover, government bodies, policy makers and health care providers everywhere including pharmacists must respect equality in access to and utilization of vaccines and medicines. It is their task to apply judicious decision-making in all aspects of access and use of medicinal agents.

4. Beneficence—intent of striving for net benefit for individual involved.

In the professional relationship between patient and pharmacist, there must be a primary focus of helping and healing the patient. This professional bond must be founded on competent practice and ethical foundations.

5. Truthfulness—commitment to openness and honesty

The care of the patient by pharmacists must be grounded in the best available scientific and professional knowledge, and must be truthfully conveyed to the patient. While there may be competing opinions on a particular aspect of care, the pharmacist must engage in applying their best skills and knowledge with honesty. In cases where there may be conflict, any judgment made would need to have due consideration around the principles of beneficence and non-maleficence. Each patient nevertheless must be approached individually, and at a level that addresses appropriately his or her needs and interests.

6. Solidarity- working toward a common social objective to keep people healthy and safe

The emphasis on human solidarity is essential in the search for survival solutions, in particular the research, production and accessibility of vaccines and appropriate therapeutic treatments. The humanism of the health professions requires that medicines become a common public good for the health and safety of all requiring such intervention. Relevant data, knowledge and findings should be promptly shared with others in order to prevent and/or reduce harm.

Working under the framework of Ethical Principles iterated above, the pharmacist holds to assuring a standard of care that meets both legal and ethical standards. While these may vary based on social, cultural and ethnic norms of a given country, the core ethical principles should be adhered to. As we examine the major facets of the Medication Use Process, we find important applications to an acceptable standard of patient care. These follow below: (Based on Galt, K et al., 2005)

1. Prescribing

Which vaccine (assuming that there will be choices) should be administered to the patients and what safety and efficacy criteria should be applied in this decision?

Which medicines should be prescribed in the mitigation and treatment of a COVID-19 positive patient?

Should only authorized medicines be prescribed (e.g. no off label use)? What about 'experimental' or 'compassionate use' designated medicines?

2. Clinical evaluation

What clinical markers establish the base level of patient evaluation for use of vaccines and/or medicines? How should these clinical markers be monitored and evaluated and used throughout the treatment process?

Are there particularly vulnerable patients for whom the vaccine and/or medications might not be suitable or recommended?

What documentation systems need to be in place for each patient which might be further used for patient evaluation and monitoring?

3. Preparation and dispensing

How will access to vaccines and medicines for COVID-19 treatment be assured to all peoples in a given country and what advocacy efforts should the profession of pharmacy be engaged in to assure an ethical foundation (including payment) for access to these agents? What consideration must be given to applying an equal and equitable payment mechanism with regard to co-payment, full payment or full subsidization in order to assure full population uptake?

Will the pharmacist workforce be effectively trained and utilized, including vaccinating patients, in order to assure meeting community immunization goals?

How will off-label prescribing and utilization of unapproved/unsubstantiated treatments be managed by pharmacists?

4. Counselling and Advising

What authoritative and clinically substantiated source of information will be utilized to guide the counselling and advising of patients, especially in a time of dynamic development of findings?

Is there a fundamental core of information that must be given to every patient, allowing for some individualization and recognition of challenges in health literacy where necessary??

How does the professions assure public and patient understanding related to the use of vaccines and authorized medicines? What special considerations must be given to patient education when using experimental or compassion use designated medicines?

What additional resources and tools (e.g. pictograms) are necessary for pharmacist counselling? Cultural beliefs and attitudes and how to deal with these?

5. Monitoring and Pharmacovigilance

What patient-specific monitoring must be in place for every patient who is administered a vaccine and/or given medicines for treatment?

Should there be a national and/or pharmacovigilance system put in place in every country to assess safety signals and adverse events?

Are there any 'black box' warnings that will be required for vaccines and/or medicines for COVID-19?

[https://yellowcard.mhra.gov.uk/assets/files/Healthcare-Professional-Yellow-Card-Reporting-Form-\(July-2019\).pdf](https://yellowcard.mhra.gov.uk/assets/files/Healthcare-Professional-Yellow-Card-Reporting-Form-(July-2019).pdf)
Medicines and Health Regulatory Authority (MHRA)

In order for a medicine to be authorised by a regulatory authority for use in the UK, the benefits and risks of a medicines are carefully considered. It is impossible for absolutely all information about a medicine to be known prior to it obtaining a marketing authorisation, so a balance must be struck between making a new medicine available to patients and having adequate information on a product's safety and efficacy. Once a medicine is launched, ongoing safety monitoring is crucial, because at the time the marketing authorisation is granted the medicine will have been tested in a relatively small number of patients for a limited amount of time in clinical trials.

The black triangle has been running in the UK for many years to highlight medicines that are subject to intensive safety monitoring. The black triangle aims to ensure that the safety of any new medicine is monitored closely. Since 2013 the black triangle has become part of an EU wide scheme and is now known as additional monitoring.

The scheme ensures that the same monitoring methods are used EU wide, so that European regulatory authorities can share the information from the individual EU countries. This provides larger amounts of information for regulators to evaluate when making decisions, and enables them to act quickly to ensure patient safety is protected, when required. For example, regulators can alert patients and healthcare professionals about newly established warnings and special precautions associated with the use of a product or they may restrict the way a medicine is used.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/396808/Black_Triangle_Scheme - new medicines and vaccines subject to EU-wide additional monitoring.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/396808/Black_Triangle_Scheme_-_new_medicines_and_vaccines_subject_to_EU-wide_additional_monitoring.pdf)

<https://www.gov.uk/drug-safety-update/the-black-triangle-scheme-or>

Supply chain and formulation



In addition to these practice and patient care related matters, the drug discovery continuum also need to be addressed from an ethical perspective. The development of a safe and effective armamentarium of vaccines and medicines should be guided by the following: (Based on FIP, 2012)

1. Issues related to efficacy and safety with appropriate information and data need to be well elaborated for professional and patient purposes
2. The vaccine itself needs to be well formulated for maximum effectiveness (e.g. adjuvants, stabilizers, preservatives)
3. Vaccines and medicines should be well characterized in order to determine supply chain challenges and how these might be understood, mitigated and resolved (e.g. temperature sensitivity)
4. Labeling, in all its forms, must be nation specific with appropriate prescriber and patient information
5. The selection of research subjects for vaccine and drug testing must adhere to well-established norms of consent and use of human subjects for research
6. Curricular emphasis in schools of pharmacy must include the most update practice and drug standards related to the prevention and treatment of COVID-19
7. There should be a single international repository for all new developments in science, practice and clinical experience which can be easily accessed by all pharmacy personnel
8. Assuring the integrity of the supply chain is paramount for all countries and must be taken seriously by both government and industry
9. How can we assure equity and equality of vaccine and drug access across all countries?

10. How does the profession of pharmacy assure solidarity of ethical commitment and professional quality across all countries?
11. How will governments, manufacturers and others associated with the economics of medication use, establish a pricing model for vaccines and drug therapies that are effective and safe for use?
12. How will pricing models be applied to the various countries in the world taking into account the nature of a given countries' economic condition and payment capacities?

A CALL TO ACTION

The International Pharmaceutical Federation (FIP), which represents over 150 national pharmacy organisations around the world, calls on governments and other stakeholders to support pharmacists and their teams as key partners in this global health crisis so that people can continue to count on pharmacists in the weeks and months to come.

https://www.fip.org/files/content/publications/2020/FIP-call-to-action-to-support-pharmacists-and-pharmacy-workers-on-the-coronavirus-COVID-19-frontline.pdf?fbclid=IwAR2cgjwprRDR_0EHV5lxS4PpgTL4LiS9RIYiqswvsbzx4If7YA09P8KHBXM
September, 2020

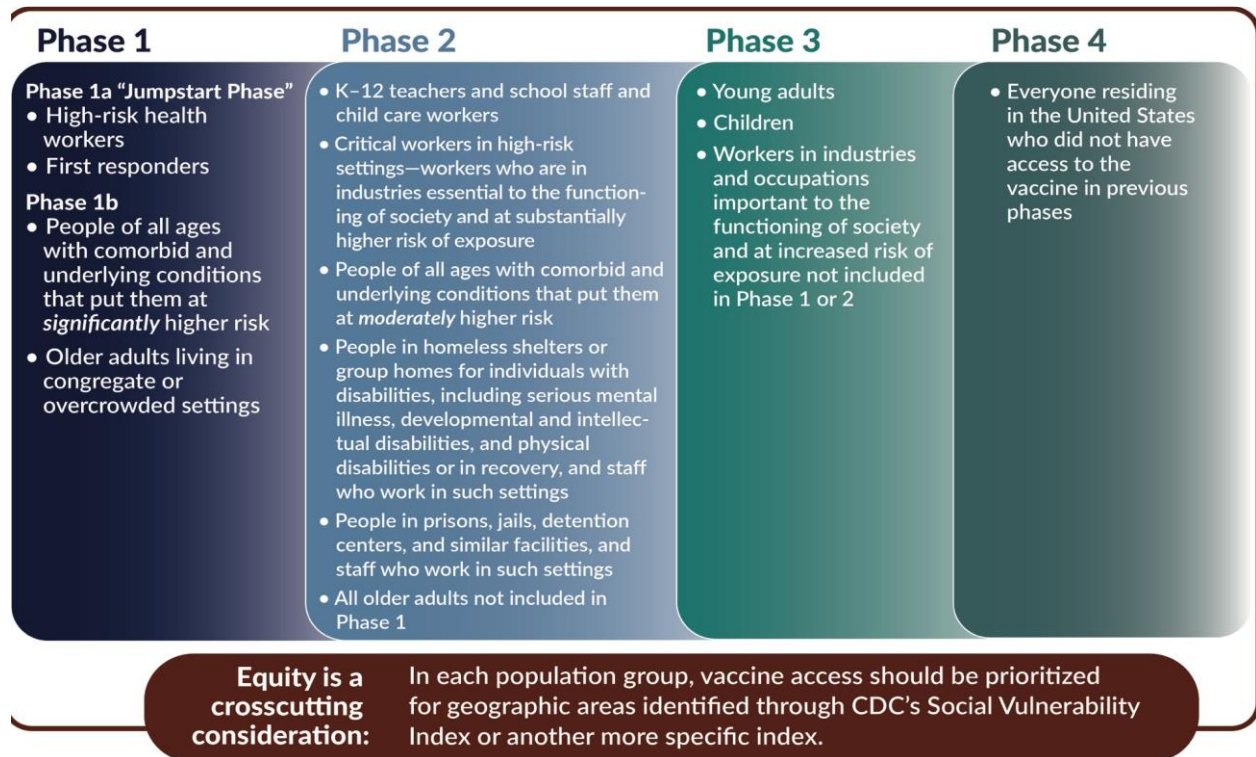
Additional Issue Areas of Consideration

1. Safety of pharmacists working in various areas/environments
2. Triaging of various services offered by pharmacists involved in different work settings
3. Deployment strategies for pharmacists on the field
4. Recognition of pharmacists as health services providers by various Non-Governmental and Governmental organizations
5. Issues with respect to willingness and consent from pharmacists to provide their services
6. Confidentiality issues for and from the pharmacist in their relationship with patients and other providers
7. support and availability of special allowances for special duty, including access to protective equipment
8. In case of death or serious injury, what should be the support provided to family of the deceased or injured?
9. Logistics and transportation of material (medications and other materials required for appropriate dispensing and patient education) in a safe and confidential manner

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10. Leadership and leadership training and development for various roles and organized efforts related to patient care and provision of pharmacist’s professional services

In so far as fair and equitable allocation of a vaccine against the COVID-19 virus is concerned, we incorporate into this narrative what has been developed by the National Academy of Medicine of the National Academy of Sciences in the United States. The priority scheme is offered below:



National Academies of Sciences, Engineering, and Medicine. 2020. *Framework for equitable allocation of COVID-19 vaccine*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25917>.

Appendix I

Suggested Readings

Sin, JH, Richards, II, and Ribisi, MS, Maintaining Comprehensive Pharmacy Services During a Pandemic: Recommendations from a Designated COVID-19 Facility, *Am J Health-Syst Pharm*, 77:18, September 15, 2020, pp. 1522-1528.

Wallis, N, et al. Frontline Pharmacist. Implementation of Field Hospital Pharmacy Services During the CCOVID-19 Pandemic, *Am J Health-Syst Pharm*, 77:19, October 1, 2020, pp. 1547-1551.

Lat, I, et al. Position Paper on Critical Care Pharmacy Services: 2020 Update, *Am J Health-Syst Pharm*, 77:19, October 1, 2020, pp. 1619-1624.

International Pharmaceutical Federation, FIP Statement of Policy: The Role of the Pharmacist in Promoting Patient Safety, The Hague, The Netherlands, 2020.

International Pharmaceutical Federation, FIP Statement of Policy: Sustainability of Pharmacist-Delivered Professional Services Through Viable Remuneration Models, The Hague, The Netherlands, 2020

Rees, H, Is COVID-19 the Long Overdue Wake-Up Call for Pharma Supply Chains?, *Industrial Pharmacy*, 66, September 2020, pp 9-12.

Appendix II

Verbatim Transcript of July 19, 2020 Webinar

Presented below is the verbatim edited script of the International Webinar held on 19th of July 2020 on the topic “Ethical Issues faced by Pharmacy Profession in responding to COVID 19”. The webinar was organized by Department of Education, UNESCO chair in Bioethics and was chaired by Prof. Russel Franco D’Souza, chair, Department of Education, UNESCO chair in Bioethics, Australia and was moderated and co-chaired by Prof. Mary Mathew, Head Indian Program of UNESCO Chair in Bioethics, Manipal, India. The webinar chat system was moderated by Col. Prof Derek Dsouza, Head Training Indian Program UNESCO chair in Bioethics. The webinar was convened by Prof. Dr. Suresh Bhojraj, President, Pharmacy Council of India and co-convened by Prof Dr. Shailendra Saraf, Vice President Pharmacy Council of India and Head Pharmacy Bioethics of the Indian Program of the UNESCO Chair in Bioethics.

The honorable members constituting the panel discussion were Prof. Henri Manasse, Dean, Pharmacy, University of Illinois, Chicago, USA, Prof. Mahendra G Patel, University of Bradford, UK, Prof. Helder Mota Filipe, University of Lisbon, Portugal, Prof. Timothy Chen, The Sydney University, Australia, Prof. Richa Dayaramani, Principal, Khyati College of Pharmacy, India, Dr. Achoka Victor Mwandale Semu, Chair, Pharmaceutical Society of Kenya, Nairobi, Kenya and Prof. Pierre EFFA, President of COPAB (Pan African Congress for Ethics and Bioethics), Cameron, Head, African Division UNESCO Chair in Bioethics. More than 130 participants around the globe attended the panel discussion, which stretched for over two hours. As the COVID pandemic has brought profound effects on all walks of life the accessibility and availability of healthcare, drugs, and medicinal substances was also challenged. The panelists presented their views and observations pertaining to how the pandemic has presented challenges to pharmacy professionals worldwide and the strategies adopted to overcome them. The panelists also unanimously felt the need for a guideline to address professional ethical challenges in similar situations. After a formal welcome address by Prof Derek Dsouza, the panel discussion was opened by Prof Russell D’Souza who presented the present status and need to address various issues of Bioethics concern in the professional and practice of Pharmacy on a global platform. Prof Mary Mathew moderated the discussion.

Prof Mary to Prof Henri Manasse

What are issues of concern that the pharmacists are facing in USA in terms of the practice of pharmacy?

Prof Henri Manasse

In the absence of sufficient therapeutic agents and vaccine there is a segment of the American society that is looking for cures in anything that may currently exist and as a consequence pharmacists are being requested by many patients either to take something that has not been

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shown to be effective or from a regulatory point of view that the indication has been approved. For example, Hydroxychloroquine presented a very serious challenge including the hoarding by both physicians and some patients of that very important medicine for patients who use it for approved indications.

Another important issue arising in the hospitals surplus to the challenges presented by seriously ill patients, they were shortages of critical drugs like muscular blocking agents, some narcotic analgesic agents and other drugs – a big ethical issue.

This raises questions around:

- Drug shortages
- Role of the industry
- Role of the distributors
- Role of pharmacists in managing the issue of drug shortages. (In many instances decisions about substitute drugs to be used instead of the drugs in short supply had to be made quickly).

We are challenged by a more **effective use of the pharmacist workforce** and through experience **in the state of Illinois in USA, the laws prohibit pharmacists from being formally designated as emergency workers**. This is an important issue because in the worst of all times where there is a shortage of personnel to manage a serious crisis and a significant portion of the healthcare workforce would not be appropriately utilized. In fact, it would be illegal perhaps to use that component of the workforce if they are not properly recognized as emergency workers. This matter was true for Chicago where they were expecting similar situation as New York City. With the help of military a field hospital was established in Chicago of 3000 beds in a Convention Centre. In order to manage 3000 bed hospital it is important to look at issues like:

1. What are the drugs that are necessary?
2. What are the fluids that are necessary?
3. What are the sterile preparation requirements in such a setting?

(worth noting: substantial pharmacist workforce is necessary to make sure that the institution and the field hospital is working effectively for patient care given that there is legal prohibition of designating pharmacists as emergency workers, the situation would have gotten out of hand without pharmacists).

Patient care would be significantly compromised which poses an important ethical issue to address to. Finally, there is tremendous anticipation now of a vaccine coming to the market perhaps by the end of the year or beginning of next year. This raises various issues with respect to access, with respect to financing, with respect to administration of vaccines and a series of other logistical matters. We have good success in the United States having pharmacists administer vaccines including pediatric vaccines. The U.S. has a very high rate of Influenza vaccination for example and perhaps because pharmacies in the community are easily

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accessible and extensively utilized. We have competent people in those facilities and therefore pharmacists make a great contribution to public health.

Prof Mary: Do the pharmacists in your country (USA) have prescribing rights so they can prescribe drugs?

Prof Henri Manasse

That authorization of scope of practice is dependent on a given state in the USA. The scope of practice is governed by the individual states so there are several states that have authorized certain prescriptive authorities for pharmacists. Some states even allow in emergency situations such as this to make changes to existing prescriptions or to switch drugs in case if certain drugs are not available. Several states recognize pharmacists as advanced practice professionals and, in those cases, pharmacists have prescribing privileges. As the profession of pharmacy in the U.S. continues to evolve in its scope and influence, it is likely that prescribing privileges will be extended throughout the country.

Prof. Mary

Hydroxychloroquine (HCQ) is produced in large amounts in India with apparently significant supplies made to USA and now it's not being prescribed in USA. Am I correct Professor Henri in saying that HCQ is not prescribed there for a COVID treatment overnight?

Prof Henri Manasse

When news first came out that HCQ might be able to stop the virus, there was a big demand and all of a sudden shortages started to occur. Simultaneously more evidence was coming out stating:

- Hydroxychloroquine has serious cardiac side effects, and its use must be judicious.
- Hydroxychloroquine was not as effective as what people first thought even though the U.S. Food and Drug Administration had given emergency authorization for the use of Hydroxychloroquine in COVID 19.
- A waning in demand was evident even though there was hoarding and several states began to pass legislation to inhibit and stop this hoarding.

Some of our colleagues in medicine were part of this problem as they started hoarding the drug in their own practices and depleting the supplies. That in turn created problems for those patients who needed this drug for other indications

Prof. Mary to Prof. Shailendra

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In India, we were as medical professionals, told to take HCQ and we are sending our medical students to the front line with the recommended dose of HCQ and they are exposed to the disease. Can you tell us exactly what is happening about HCQ?

Prof. Shailendra

My personal observation is that there is no mature behavior from any agency as far as the use and the restriction is concerned. A paper is published in Lancet overnight without any verification and next day there is another advisory coming up. When we had this particular one for the terminal cases and again we bid on and there was international pressure to promote one particular drug and that condition, this particular HCQ was removed from the weaponry to tackle the problem between the terminal cases of COVID 19 and another was proposed.

In addition, in similar cases there are a number of reports pouring in about the repurposing of drugs without any serious risk benefit assessment in terms of using and recommending the drugs to the patients. In India pharmacists are not empowered to write the prescription nor are they empowered to change the prescription. However, we can change the brand name with the generic version. **There is need for guidelines at least in cases of emergency SOS conditions or Pandemic.** It seems that there is no consistency of policy making and this is creating problems as far as the ground force is concerned **because there is a dilemma for everything.**

Prof. Mary to Prof. Shailendra

So, what is being prescribed now? Today's paper says that Dexamethasone is very powerful

Prof. Shailendra

When we want to subside the acute reaction we can give critical drugs but with consideration of different ethical issues involved. **So, there is no perfect treatment.** Everybody is giving treatments based on their own knowledge and with their own risk - benefit assessment. Hence there is a need for:

- Some sort of policy that we have to discuss and evolve so that we can empower the doctors and the frontline workforce to have the experiments-based on different variables – so important because in a country like India we have a lot of diversity, variations, faiths and beliefs and we are just dealing with a single drug and that is also not proven efficiently

Prof. Mary to Professor Timothy

Do pharmacists and pharmacy professionals have the prescribing rights in Australia?

Professor Timothy

Pharmacists currently don't have prescribing rights in Australia for prescription medicines

Prof. Mary

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Currently which ones are being used for COVID 19? Can you tell us something about the off-label drugs and what is happening in Australia right now about pharmacy practice?

Professor Timothy

There is quite a lot of research underway. Off-label use refers to use of a medicine for an indication for which has not been approved by a regulatory authority such as the Food and Drug Administration (FDA) or in Australia the Therapeutic Goods Administration (TGA). This means there is no safety or efficacy data in relation to the use of that medicine for an alternative indication. Quite a lot of the papers and discussions have been about the repurposing of medicines for different indications. We have spoken about examples of HCQ and Dexamethasone and when we are thinking about off-label use of medicines. In fact, we should really think about these in relation to an alternative and effective treatment?

Important consideration:

- Could these individual patients be recruited to a clinical trial of a repurposed medicine? In the absence of that then individual consumers and healthcare professionals really do need to come to a shared decision making approach as to whether random off-label medicine is appropriate or not and this is a really significant issue
- If the off-label medicine is prescribed and used then there is a significant need for monitoring for documenting and sharing the experience with other people to comment.

Prof. Mary to Professor Timothy

What are the other off-label drugs that are being used for COVID19 other than HCQ or Dexamethasone or is there anything else that will be there?

Professor Timothy

We have had some interesting developments with Remdesivir - the antiviral medicine. At the beginning of the pandemic it appears that Remdesivir is valuable in reducing the number of days or reducing the duration of symptoms for people who have significant symptoms associated with COVID 19. However, I think the studies suggest from 15 days to 11 days in relation to days in terms of a reduction in the symptom period for individuals. One very interesting thing in Australia recently you said is the Therapeutic Goods Administration, our major regulatory body that has fast-tracked the approval of Remdesivir – a shift from an off-label use to a regulated use for that medicine. I believe this is an **important milestone in relation to changes in regulatory policy in the context of an acute pandemic situation**

Prof. Mary to Professor Timothy

My understanding of the Australian health system is that for most of the population the government pays for it?

Professor Timothy

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In Australia we have a **pharmaceutical benefit scheme**, which is essentially a **co-payment scheme so if the individual is in primary care then the individual consumer would have a co-payment for the use of a particular medicine.**

In case of Remdesivir in the hospital setting there would be no charge to the individual patient as hospital setting there is no direct charge

Prof. Mary to Dr. Achoka Victor

For developing countries and underdeveloped countries patients cannot afford this treatment. The remedy in this case is very expensive in India. Africa started a little later than the rest of the world. How is it in Kenya and what is the treatment being given for COVID 19?

Dr. Achoka Victor

In Kenya yesterday we reported the highest number from a sample size of around four thousand five hundred and we're able to get 688 cases. That is quite alarming because in the recent past to be getting very low numbers, so we know that all predictions are pointing towards a major spike sometime in September. Our first cases were reported in Mid-March around the 12th, so we are bracing ourselves for what is to come and in our neighboring countries Tanzania has not been reporting any cases. The government went on record and said there are no cases of corona in Tanzania.

In Uganda there are slightly over a thousand cases so that creates a logistical challenge considering a very porous nature of the Tanzanian border. The mortality rates are low here. Regarding the medications that are available for the management of COVID 19 – currently we have very few patients on critical care the mortalities. In total we've had around 100 to 200 mortalities so far, and considering the disease is not only respiratory they are using blood thinners in Morocco and vitamin C and steroids.

There was a massive shortage in Kenya and by the time we start getting the cases already a lot of these drugs were already been held so there is nothing even to buy. This was happening in multiple levels. You are talking logistical but it was the same with even importing it. Most of the inputs come from India because you only had one brand of this drug in the market for drugs like Remdesivir.

Currently we are trying to complete part of the import registration process and going to get this molecule from India. If I am not wrong the product is not even in the market. Right now, we are doing more **supportive care**, and you have rightfully pointed out it's going to be a major challenge cost-wise for new molecules

Prof. Mary to Dr. Achoka Victor

Do pharmacists have rights to prescribe drugs there in Kenya?

Dr. Achoka Victor

There are quite a few grey areas. The number of pharmaceutical outlets in the country are so many, because you have different levels of practice. We have pharmacists before and above clinical pharmacists. We have lower academia where there is a diploma status like certification in pharmacy assistance. There are many colleges which are training these low academics. So despite the best of efforts from our regulatory bodies to try and regulate these outlets this has not been possible. Many of these outlets run so whatever you want you could easily walk in and carry as much of product that you wish for. Still things are much better than they were in the past let me say that.

Prof. Mary to Prof. Mahendra Patel

What are the issues in front of pharmacists in pharmacy practice in the UK?

Prof. Mahendra Patel

Very important discuss Bioethics around the global perspective and how we can bring things together. It is important that we have:

- A streamlined and uniform approach with greater focus and need to standardize things bearing in mind the differences in policies and regulations within different countries in terms of legislation, practice and education.

In the UK what we have had are the issues around an initial shortage of drugs but also a highly committed and dedicated pharmacy workforce across all hospital, primary care and community settings. This has played a huge and crucial role especially in meeting with the unprecedented onslaught and high demands during the particularly early phases of the pandemic. There was considerable concern also of working with a depleted and unprotected frontline workforce causing low moral accentuated by delayed remuneration. There was also anxiety with people running to the pharmacies, stocking up just to make sure they've got sufficient medication in preparation for the inevitable national lockdown. Therefore, not surprisingly this initial knee-jerk reaction caused a temporary shortage within the supply stream.

It was not a shortage from the manufacturing side necessarily but more the delivery system itself being clogged up. Whilst we overcame that I was wondering that perhaps in view of another spike arising then:

- How can we look at better catering for our patients and public at large where there really is a shortage. Perhaps there is room for some consideration for where in special circumstances re-using drugs returned to the pharmacy where they have not left the premises? For example hospital settings, care homes, hospices.

In the UK pharmacies often receive returned dispensed medication from a safe disposal perspective for a variety of reasons including when a patient has passed away or they have changed on to different treatment etc. Is there a mechanism that can be suggested whereby we can safely recycle those medications to avoid any backlog issues in the future especially pertaining to supply system problems?

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I know we are different in different parts of the world but is this something that we could **consider and is it something that we could standardize in some form** in preparation for another pandemic or similar urgency or emergency?

We talk about another resurgence potentially and with the broader learnings from the COVID pandemic and how can we make things more efficient, more effective, and safer for patients and public at the same time?

So how can we ensure that the delivery and continuity of services and supplies and provision to the patient is maintained without extra and undue anxiety and stress?

Prof. Mary to Prof. Mahendra Patel

If the government had said that the pharmacy would remain open then we could have probably avoided this panic because it was a complete lockdown, a complete shutdown, which made you know this forced people to go into this kind of panic mode and hoarding?

Prof. Mahendra Patel

Exactly – Missing strengths and missing quantities on prescription can however be ordinarily be changed the pharmacist. However, one of the other things that we have in the UK is now allowing the substitution of medicine – so that when a medication is prescribed by brand or requesting a particular pharmaceutical form, the regulatory requirements are to be relaxed in certain situations where they can substitute on their own accord. They don't have to wait to get the consent of the prescriber and is where the skills, training and professional expertise of the pharmacist is made to good use. Pharmacists in the UK undergo a five-year programme of education to become competent in practising as a qualified pharmacist.

Is there something from a wider global perspective that could allow us to substitute?

This is also causing less tension on the patient waiting unnecessarily by not having their medication, waiting for the doctor to come back and confirm. I as a pharmacist can change to a different brand or pharmaceutical form e.g. capsules instead of the tablets etc.

Simple things could be a very enormous help to the patient but again as we know, the efficacy, the bioavailability may be different in some instances.

- Considering the ethical aspects of how does the patient feel about this?
- How does it affect the patient's clinical response in some instances?

Perhaps this is an area where we can look at in a wider and more uniform manner from a global perspective? An opportunity of how we can utilize the role of the pharmacist and the skills of the pharmacist even better?

Prof. Mary to Prof. Suresh

About the issue of hoarding and shortage of drugs can you tell our panelists what had happened in India?

Prof. Suresh

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When the lockdown started off in most of the pharmaceutical companies they very clearly said despite the challenge that may be there in importing materials from China for some of the raw materials they can continue to supply these medications for next three to six months so there was never a challenge before the country as such what is going to happen if the medicines are not going to be there so this is very important for us to understand now. Second point is regarding the people's reaction, it is a normal reaction when somebody says tomorrow all restaurants are going to be closed and our first reaction is to go and buy whatever we can irrespective of whether we need it or not, it's a human reaction which we cannot prevent but once they settle down to the normal routine they know that yes there is no challenge and people become little more relaxed.

Prof. Mary to Prof. Suresh

What was with Paracetamol that they are regulating now in India – taking down your phone number if you require a Paracetamol?

Prof. Suresh

It is a misconception that is there. The availability of raw material for manufacture of Paracetamol tablets, the Active Pharmaceutical Ingredient (API) that was required was being imported from China all along, because it was cheaper. As a result now as soon as the reaction was that that we cannot import or may not be able to import the quantities which we want immediately, the API industry started working in manufacturing those APIs that are required for. I mean API in the sensor active pharmaceutical ingredients that would be required for the Paracetamol. They must take the phone number as a caution for two reasons:

1. If you are taking Paracetamol you are taking it because you want to lower your body temperature - YES so one of the indications for such a step is that if you are suffering from corona infection an immediate reaction is that your temperature will increase, your throat and other related issues will start too. So they want to track patients who have taken Paracetamol without prescription to make sure that tomorrow if there is a need they can reach out to them and the point of contact is to be noted who has purchased, why they purchased Paracetamol.
2. No that is the more the reason rather than not a parasitic amount not being available for the person.

This is the basic reason when some of these drugs relating to symptoms relating to the corona was for being purchased in the pharmacy. People wanted to make sure they know who is buying it, and why the person is buying it, so that the health officers, the drug authorities were routinely checking these issues which are required.

One more point to add here which you mentioned earlier was **the re-supply of drugs back to the pharmacy**. I think that that can happen only in where the supply chain is secure like if it is a case of in a hospital setting if the medication is given to bedside and then brought back to the pharmacy it is okay because the medication did not leave the side of the practice where it is there. However, if today a patient takes the medication home and then comes back to the pharmacy to give it back that is not permitted. The reason being we do not know what the supply chain and tomorrow is there may be some adverse effect as a result. This is the reason

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why no pharmacy can legally take back the medicines once being sold to get back into the pharmacy for reselling purpose.

I think this is a very important factor – **so this is not allowed in India**. It is possible though some may be practicing in this manner but legally they are not supposed to do it.

Prof. Mary to Prof. Helder

What is the issue of pharmacists and that of pharmacy practice in Portugal? Are pharmacists given prescription rights?

Prof. Helder

I don't think that we need that that right because the access to the prescribers is easy. We have a National Health Service (NHS) that is universal, so people go to the doctor and then visit the pharmacist. I have the role of dispensing the prescription and we don't need to have prescribing rights in our system. We don't feel that this is our main goal in the next future because there is good access to doctors and to pharmacies. There is no need for this to happen in Portugal.

I'd like to come back to share what is my impression on this, because I was involved since the beginning on the Crisis Working Group on COVID. I would like to underline two aspects:

1. Pharmacy is a scientific profession and therefore we should do things based on scientific practice and reasoning. Yes, there is an ethical issue involved with the beginning of this pandemic where we were part of the treatment of patients with medicines that did not have any prior evidence of use on such patients. So off-label use was the situation because we had no established knowledge about COVID, so it was difficult to choose the medicine. We had many patients treated with medicine that there was no proven evidence for this. You tend to use what you think can work because it works in similar situations or because of to use this is probably the right thing to do. **It is important to start clinical trials urgently to generate evidence** and this is this was now done now.

World Health Organisation (WHO) has the solidarity clinical trial which is a very pragmatic clinical trial with some results now coming up. That is the reason why we decided not to use HCQ anymore because of no evidence regarding its efficacy and the safety. This can become a problem and we must incorporate the results of the clinical trials that are in place now. From the pharmaceutical point of view this is very urgent.

2. Another is the non-COVID patients like oncology patients and others with very serious conditions that are not coming to hospital because they are afraid of contracting with the virus. They don't have access to medicines in hospital pharmacy because they are afraid to go there. In Portugal we tried to solve at least in part a problem with the community pharmacies so that there was a plan working together with hospitals to make patients to have access to this so that the supply chain is not broken. The supply chain is coming out now and it's changing to the community pharmacy.

I think that we as pharmacists have to learn with these experiences in order to propose the future role of community the role of community yes patient-based and with a much bigger and much important role of community pharmacists and community pharmacy on the supply of care in order to give more access and more care to the patient

Prof. Mary to Prof. Helder

Pharmacy is not given recognition or importance even though they're very important in the healthcare system as that of being the frontline workers which I think this pandemic should now change that view - even pharmacy practice has to be part of the frontline care?

Prof. Helder

In Portugal pharmacies are one of the professions more recognized for the population so we have a very good presence of pharmacies. We have at least three – in my case the mean is three pharmacists per pharmacy. Pharmacists can vaccinate and administer medicines, so the public is favoring and asking for more and more pharmacies.

Prof. Mary to Prof. Pierre

Just like in India, I am sure in Africa also there are medications which are not proven but people have more faith in medications which are not allopathic. So how is the situation in Cameroon? Do you know if in this pandemic people were taking medications which were not recommended by the doctors which were not allopathic?

Prof. Pierre

This COVID 19 it's a health problem – YES but that health problem became a political problem. The pharmacy profession is **facing a huge challenge to show to the public that this profession is a profession of health workers**. Of course, it has some aspect of commercialism but it's deeply a health profession.

When the government starts dealing with the team of the emergency there were only a few pharmacies not enough at the start. Things are moving because in our country, as with many other African countries, pharmacy at the beginning was not a healthcare profession...it was a commercial profession. **Then with all the efforts of WHO and the International Federation of Pharmacists and things are now moving.**

The first thing was to manage the curricula in all the pharmacy project training of pharmacists in African countries. African pharmacists trying to propose a common curriculum and is done with the African Pharmaceutical Forum which links the African branch of the International Federation of Pharmacists and Ministry of Health. The law on pharmacy is a health law and you can have the diplomacy to allow you to administer the vaccine. We have inquired recently from the sector the pharmaceutical sector, the national pharmaceutical sector, and a lot of people are using also African traditional medicine. This is not official. Of course, we have rules from WHO but it's not really an agreement it's a sort of accommodation from arrangements to

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officialise the medicine from the traditional sector. However, when we have the COVID 19 most of the people went to the traditional medicine and the politics on HCQ and the big pharma testing vaccine did not help at all applicants on this point of view – because who do we trust now? We don't really know what to do and then just waiting. The international community needs to find a solution. There is too much, too much discussion of money, big pharma companies. **Now it is time to enhance research and production of medicine from the African tradition.**

Prof. Mary to Prof. Richa

Can you brief about the practice of Ayurveda medicine in India and its role during this COVID 19 pandemic?

Prof. Richa

India being a vast country and full of diversities there were so many bioethical dilemma situations especially for the community pharmacist. First of all, I wish to bring forward a couple of concerns of bioethical dilemma that the community pharmacists were facing.

When they are dealing with so many patients or the customers who are coming to buy the medicines, and initially in **India we had witnessed that there was a shortage of masks and protective gear, so the pharmacist they themselves were at risk. It was a situation that needed to be addressed** and there was a feeling of fear and anxiety that was existing in the pharmacist community as well because they did whatever like they could because there was complete absence of guidelines and protocols on how to tackle this situation and how to work. Initially many pharmacies were closed but slowly they could by their own intelligence logic, devise methods and means for social distancing. Then they started functioning and started dispensing the medicines.

In hospital setups we had witnessed the situation where **everybody ran away initially because out of fear. There was not any protective equipment available, so they were concerned about their own safety.** There was a complete uncertainty and **lack of appropriate facilities – even receiving cash because in India the digital system of payment is not very common** at the grass root level. In hospitals and private clinics, cash is the common means of transaction – **a point of concern that the collector and the whole staff with the risk of COVID infection. The concerns then are multiple: who will take the cash, who will diagnose, who will perform the procedure and be exposed to the biological fluids and what about management of biomedical waste and handling dead bodies?**

Prof. Mary to Prof. Richa

Dr Richa can you tell the panelists what AYUSH is?

Prof. Richa

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AYUSH is a department like for Ayurveda Unani Siddha Homeopathy. Also all the alternative therapies it comprises of but largely Ayurveda, so naturopathy and Ayurveda actually in our India it is traditionally only it is imbibed in our day-to-day living e.g. we are using so many spices and condiments and other things and now of late we are saying that **green tea is also effective in building immunity.**

Prof. Mary to Prof. Richa

You know the older generation their faith is all on Ayurveda?

Prof. Richa

Yes – because that is very ethno pharmacological in nature. Traditionally we follow that all over India and I think 80 % of the global population also believes in traditional medicines and treatment like in India they believe in Ayurveda and naturopathy which are mostly used for preventive and prophylactic treatments or for immune boosting mechanisms.

Of late we have also witnessed persons who are not in contact they don't have any travel history, but they are also reported to be infected positive. Initially it was thought that climate may play a role in the COVID and the curve will be flattened after a certain period. Yet now we can see that it is almost more than half a year we have come and still it the cases are increasing daily. We are in a state of **global dilemma**, where everyone is trying to understand the behavior of the virus and the infection, cause, pathophysiology, and epidemiology.

Allopathy is also not evidence based in treating COVID and yet we don't have any perfect medicine for corona, because this is the third in a row for such a flu virus after SARS and MERS. Its almost 18 years since 2002 when the first case of SARS was reported but still after 18 years at a global level, we have failed to address this flu.

All over the world fast track approvals for clinical trials already in line, there is **concern was for the volunteers they are recruiting, their COVID history, management, testing etc.** The diagnostics and treatment are not available in adequate number and affordable price. **Also, there is no guideline issued from Central Drug Standard Control Organisation (CDSCO) to address the COVID testing before creating the volunteers. There are no criteria as of now available for conduct and compensation.** Suppose during the infection there may be some asymptomatic volunteers, and somebody may come out with a COVID infection or some name what is to be done in that situation, so it is very tough decision. For one drug we cannot stop or suspend the research for all other drugs.

Pharmacists were also the first line of response that was available to the common public or community. There was a shortage of healthcare staff and so the immediate response that was available to the community is the pharmacist. Counselling by the pharmacist is very important role that Pharmacist has played during the whole of this pandemic. Some of the few important aspects that are of dilemma

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- Withdrawal symptoms for addicts, people visiting pharmacies for information on medication or other including **contraceptive devices, contraceptive pills, MTP kits, co morbid and terminally ill people for their regular supply of medicines**
- Risks to pharmacists, doctors and nurses for acquiring COVID
- Mental stress faced by pharmacists being the frontline professional.
- Aggression by public towards pharmacists due to non-availability of medicines. **So there is a lack of protection and support for community pharmacist.**

Prof. Mary to Prof. Richa

What are ethical issues in recruiting participants to the COVID challenge study?

Prof. Richa

In my opinion it is like choosing between bad and worse... so it is a point of discussion or concern that how much it is ethical or justified to infect a healthy individual with the virus to test the virus but then there is a **risk benefit assessment that needs to be done** and clinical researchers govern under the basic principles of bioethics – so they are educated, they are told, they are informed and the principle of autonomy is in place.

Prof. Mary to Prof. Timothy

Can we have your opinion on the COVID challenge?

Prof. Timothy

There should be all the same principles and processes which apply to any human ethics committee approved research, so there must be a statement.

Prof. Mary to Prof. Timothy

Let me just put a point to you that we are at a situation where people have no work, they have no means of earning their living, and this may be one of the ways to earn a living ... can we have your opinion on this?

Prof. Timothy

I think this is a very complex issue and a very significant issue. I think if something like this is to be a supporter then for sure there needs to be really a significantly informed consumer in this process, because clearly it's not without significant risk in the proportion of individuals for a proportion of individuals. May be the symptoms experienced of COVID 19 might not be yet too severe but for some proportion of individuals it could be the worst possible outcome for them.

Prof. Mary to Prof. Helder

Can we have your opinion on the same issue?

Prof. Helder

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I'm a member of the national committee for clinical research in Portugal so I'm very sensitive to this. What you have mentioned is correct.... if a person needs money that is a reason to go. This is what happens with every clinical trial. **There are no clinical trials without risk** so what is important is to be sure that informed consent is there and the conditions are created to avoid that people go and take the risk just because they need money. For instance, **in my country of Portugal it is forbidden to pay people to enter in clinical trials but that is not the same all over the world. What is important is to be sure that all the ethical principles are considered.** I tend to believe that this study can only be approved after an ethical committee consideration to be sure that all the ethical principles are there.

Prof. Mary to Prof Henri Manasse

Can we have your opinion on the same issue?

Prof Henri Manasse

I would answer in the affirmative. Yes. However all ethical guidelines for clinical research in human subjects must be followed and the patient must be fully informed. Patients must be fully volunteers and they must fully understand all the risks associated with the trial. I think it's important to continue such clinical trials because we wouldn't witness the advancement of medicine if we didn't have willing volunteers. I believe the work that's been done in the last several decades to protect human subjects in research should allow us a good foundation for vaccines clinical trial.

Prof. Mary to Prof Mahendra Patel

After all smallpox vaccine was discovered that way – you inject the virus and you got the vaccine. What is your opinion professor?

Prof Mahendra Patel

We have to absolutely be sure that the person is well informed as to that they may be consenting to. We've received consent **but did they actually understand what they're consenting to.** I think that it could have a huge difference in terms of how people feel. If whilst we try to make it clear as possible in our minds, we think we've been very fair and upfront that there's a payment, we don't know if it's going to be effective, we don't know if there will be an interaction etc, all that information but how well do they understand that? Are they of reasonable and sound mind? What exactly is that?

I think until we do not get that point across clearly and in a manner that the different communities, organizations, the public and patients understand then I think it becomes unethical particularly with a payment attached to it.

So in the UK I have highlighted this and one of the things I'm championing particularly within the minority ethnic groups where there's a reluctance in relative terms to take part in research and trials, **is how do we get them to engage into the studies/trials more?** We have to give the

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same message that we would for everybody else as well but are their understand the same – so in some communities there's a **cultural belief** here that we don't want to engage in the vaccine but then in some parts they will say well actually there's a vaccine going let's go for it before they run out. So, it's how well informed they are and providing the person taking part is absolutely sure what they're taking part in is and what it entails then it is absolutely okay.

Prof. Mary to Dr. Achoka

What is your opinion in this regard?

Dr. Achoka

We've been doing this for malaria. The strain of malaria that we have in Kenya is one of the last strains in the world and we've been doing human trials and randomized trials. The key here is informed consent. The only issue would be at times is how this information is disseminated to the public. Like Professor Pierre said there was a major pushback on this, and the reason was that it was thought that they would want to experiment on Africans and not on the European underdeveloped countries. So, I think how the information is disseminated, how it's passed down to the masses and the informed consent again very key.

Prof Shailendra

The society has witnessed big war where the wars were fought to restore peace. The interpretation of law is above the law because interpretation is always contemporary in order to keep the ball going you're talking about, yet this study so we should go ahead with such type of experiment based on certain issues we cannot stop these search ups are some new drugs and molecules.

Prof. Mary to Prof Timothy

They've just started the first stage of vaccine trials so what is your opinion on issues involved?

Prof Timothy

Thinking about the global scale we would need multiple of those vaccines to be shown to be both safe and efficacious and scalable. I think the critical ethical issues are - who has access and at what cost for these vaccines

Prof. Mary to Prof. Helder

What is your opinion on issues involved?

Prof. Helder

There must be international agreements and commitments in order to not give conditions for the ones that are in need and not for the ones that can fight. I think that the **pharmacist can have an important role as well on the quality of the news of the information**. Often we are facing a number of information that is of poor quality and is making people very anxious, and I think as professionals we have these obligations to try to give the right information and not help people to choose what is right and what is rubbish.

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Prof. Mary to Dr. Achoka

Who do you think should get the vaccine first?

Dr. Achoka

The ones who need it the most, that is the most exposed – the health care workers. We would start probably with the elderly healthcare workers, but we need to have guidelines for that based on demographics, age, illness and other issues.

Prof. Mary to Prof. Richa

We have a vaccine claimed by the Indian Council for Medical Research (ICMR) that it's going to come out very soon. What is your opinion? Are they fast tracking it because they're saying by August we should get the vaccine is it possible?

Prof. Richa

I'm sure – of course all the clinical research for in the backdrop of COVID is fast tracked only we are also eagerly waiting. I guess it will be around January 2021.

Prof. Mary to Prof. Richa

We've said the place of pharmacy practice is very important and they should be acknowledged in the health healthcare workforce. How can we take this forward and make your presence felt?

Prof. Richa

We should realize the fact that pharmacists have now been well appreciated in the society and in the community for their services. Earlier it was just like the pharmacists are for manufacturing the medicines, but now various domains of their activity have been brought into the limelight and now they are accepted and accommodated. Also, **we need certain guidelines and protocols** because frequency of such pandemics is increasing. So we definitely need the protocols for use, triage, for the management, for the prophylactic, for the means we can have, for the viral infections, for the bacterial infections, for the parasitic like that we can categorize and if there is no body for COVID 19 we need to take a stand. **We also await a kind of triage protocols for the vaccines and management of current pandemic.**

Prof. Mary to all

Your last two thoughts on the role of pharmacists or pharmacy practice.

Prof Timothy

Pharmacists should be key members of multi-disciplinary teams. They must be **practising evidence-based medicine**, this is in terms of the advice they are giving and their actual practice. The **goal of the pharmacist really should be for the benefit of the patient** with respect to the safe and efficacious use of these of medicines. These are core principles for the profession of pharmacy, which I think is central especially in a year time of pandemic like COVID 19.

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Prof Pierre

All the health professionals to have a platform discussion on all the issues of public health yes and we hope that through this platform we'll be able to have a good dialogue on all the issues

Professor Helder

Pharmacists shown the role in this crisis and so it's important to use this experience and this evidence to show the politicians that pharmacists can do more that they are doing and but they need to be recognized in every dimension. So I think that pharmaceutical organizations now have now a role to play in order to show how pharmacists can help to increase the quality of the health system so it's on our hands to show that and to make the step forward.

Prof. Mahendra Patel

I think this platform has a clear setting in terms of **developing guidelines and strategy for the vaccinations**, and who it's for, and how we can make sure that it is equitable. I think that is critical so that we don't widen these inequalities that we continue to witness throughout the world and for decades and centuries.

Just to mention if I may, that we need to start looking at the curriculum. I didn't want to bring in the curriculum because of time but just want to park that thought that becomes key in terms of lifting the wider agenda around **ethical dilemmas and responsibilities**.

Pharmacists should never be seen as mere shop-keepers or compounders anymore.

Dr. Achoka

In a third world country where you're trying to achieve Universal Health Coverage (UHC), I think the pharmacists should be empowered to carry out some **basic clinical work which they know, and they've been trained on**. I think **they should be enshrined in law** and should be allowed to do a little bit more than they are being limited to do right now.

Prof. Shailendra

While the pharmacists were delivering their services at the bedside with the doctors, they were also working day and night in the industry, in dispensing of medicines and at the same time, they were addressing in various other roles like of a teacher, medical representative and others. They have performed on all walks of their profession so they command the respect and they deserve it. My suggestion for this session to conclude is that **pharmacist should also be included in policy making**.

Prof. Gita Laxmi

There was a talk on the AYUSH and about the modern medicine which I think so in future we have to integrate these kind of medicine to put into use so that we could get a wider kind of treatment and faster recovery period so that is what I wanted to tell and so it has to be integrated. The second one I want all the **pharmacists to be associated with the clinician and not to separate themselves into the pharmacy or the shop or the pharmacy** which exists in a

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hospital, so they always have to associate themselves during the clinical rounds and meet those clinicians each and every day to know what is the treatment protocol given to the patients in their ward or wherever they are practicing. This what I wanted to say for the pharmacist, and of course in India the medicines are in supply and there is no dearth of supply of medicines. I also want the pharmacist in India to manufacture their own raw materials and ingredients which are used to manufacture the tablets or injection or vaccines.

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