A 101 on the IHR and the Pandemic Instrument

With Nithin Ramakrishnan and Vanita Nayak Mukherjee.

Vanita Mukherjee [00:00:04] Welcome to the Feminists for a People's Vaccine podcast, a space for imaginations, discussion and feminist analysis from the Global South. In this creative journey, we approach the tough questions brought to light by the pandemic. Join us to look at this once-in-a-lifetime event as a passageway to imagine a fair and just world for all. In today's episode, we focus on global health emergencies and the challenges facing global health governance.

In today's episode, we focus on global health emergencies and the challenges facing global health governance. The World Health Organisation has declared that COVID-19 is over as a global health emergency, but it is not over as a global health threat. Here is what the Director-General of WHO, Dr. Tedros, had to say.

Soundbite - Dr Tedros Ghebreyesus [00:01:07] For the past year, the Emergency Committee and WHO have been analysing the data carefully and considering when the time would be right to lower the level of alarm. It's, therefore, with great hope that I declare COVID-19 over as a global health emergency. However, that does not mean COVID-19 is over as a global health threat. As we speak, thousands of people around the world are fighting for their lives in intensive care units, and millions more continue to live with the debilitating effects of post-COVID-19 conditions. This virus is here to stay. It's still killing. And it's still changing.

Vanita Mukherjee [00:01:58] COVID-19 still remains one of the most devastating pandemics the world has ever seen in recent times. It has deepened inequality and played havoc on all aspects of people's lives. The pandemic spotlighted an urgent need for global solidarity, cooperation and
collaboration across nations. Yet, what we witnessed was a yawning gap and a deep divide in access to diagnostics, vaccines and therapeutics between the developed and developing countries.

What are the current mechanisms and processes in place to deal with global health emergencies? Do they adequately address a complex set of challenges for global governance and multilateralism? Do they shift the needle from inequity to equity? To discuss some of these questions. Our guest today is Nithin Ramakrishnan, a lawyer and social advocate with the Third World Network. Nithin holds a postgraduate degree in international law. He tracks and analyses key issues at stake that emerged from the negotiating processes for global health in the World Health Organisation. Warm welcome, Nithin, to the FPV Campaign podcast.

What is the history and origin of the International Health Regulations or the IHR 2005? Can you explain this for our listeners and highlight some of the rights and obligations for the WHO member states?

Nithin Ramakrishnan [00:05:06] In fact, thank you for being willing to talk on IHR 2005 and its amendment process, while most of the global health experts are busy keeping track of negotiations for a new Pandemic Instrument. As a response to your question, International Health Regulations 2005, otherwise known as IHR 2005, is the only binding international legal instrument enabling WHO and its member states to be prepared and provide a coordinated response to health emergencies like COVID-19. It requires Member States to develop certain capacities: detection, reporting and communicating with WHO, and also to provide a response to such outbreaks. WHO, as a directing and coordinating authority in international health work, is obligated not only to provide technical assistance to member states in capacity building and strengthening but also to provide an internationally coordinated public health response to health emergencies, which they determine as a public health emergency of international concern. WHO is also obligated to mobilise resources, including finance and technology for the above-mentioned purposes, especially in assisting developing countries. Now, all this sounds great, but the devil, as you know, is in the details. The particular forum, like the governing body of international organisation or an international court, uses hard law obligations on surveillance and reporting to WHO. But it, on the other hand, uses soft law obligations when it comes to international cooperation and assistance.

Vanita Mukherjee [00:05:07] So let me get this straight, Nithin. IHR allows for both the use of hard and soft laws selectively. Hard law for surveillance and reporting, but for the more important piece on cooperation and assistance to combat a disease outbreak that is soft law with little or no accountability. Can you elaborate a little bit more on that?

Nithin Ramakrishnan [00:05:30] For example, a state which detects and disease outbreak which has potential to raise international concern, must inform WHO within 24 hours of assessment of the situation. Now, the provision which provides so in IHR 2005 is a hard law. If you get to know when a state became aware of the disease outbreak in its territory, we can calculate whether it notified WHO within 24 hours. If they haven’t, f they haven’t, WHO can clearly say that they have not performed their obligation. Perhaps, one of the other state party can hold this particular state accountable for the loss it's suffered due to the said omission. Now, on the other hand, let’s take another example from IHR 2005, which maintains that when requested by WHO, states could extend some support for performing the WHO-coordinated activities in response to a health emergency or a disease outbreak.
Now, this provision, which speaks so in IHR uses a soft law approach. This means each state could take a set of actions in support of WTO activities or maybe choose not to do certain activities, which would go contradictory to the objectives of the WTO action or policy, and then claim that they have supported WHO in its international response. We have examples from COVID COVID-19 pandemic. For example, if a state has purchased vaccines ten times its population and could still claim that it has delivered on its obligation by simply donating vaccines nearing expiry in each batch of procurement. So this is the problem of soft, low, hard, low approach.

Vanita Mukherjee [00:07:15] So how did such a system come about?

Nithin Ramakrishnan [00:07:19] I think the reason could be the whole regime as a colonial legacy. Partly is deliberate and I would say partly being structural and using a colonial lens. So IHR 2005, I would say, is a revision of health regulations, which was adopted by the World Assembly in 1969, and these health regulations are in itself restatements or revisions of international health instruments called Sanitary Regulations that predate even WHO. The first sanitary regulation was adopted during the 1850s. They were meant to inform the governments of colonial masters that there were some disease outbreaks in the colonised territories, so they can or they must quarantine and sanitise the goods and persons coming from the colonies to the mainlands. So the change from sanitary regulations to health regulations is important to note because it marks the decolonisation of these regulatory instruments. Again, it is important to know that this decolonisation was partial and incremental, it was not complete. Several structural elements of colonial prejudice against colonies or against the people living in the new independent developing countries persist in IHR legal provisions, not only in the legal provisions, but also in the way of thinking in implementing these laws or how to implement these laws. For example, as civil society observers in WHO and WTO meetings, many times we have heard this argument from the developed countries. I quote: “Oh, we know, right? These countries who cry for technology transfer will start the production of vaccines in their countries cannot produce quality vaccines”. End of quote. This really reflects colonial and racial thinking many times, and that is what is actually leading the design of international help.

Vanita Mukherjee [00:09:21] It’s also very interesting to sketch out where the emphasis is. Even though they had changed the name from sanitary measures to health, the emphasis is more on snooping and surveillance and less on cooperation. I think this raises a bunch of questions. A review committee submitted a report on the functioning of IHR 2005 during the pandemic. Can you explain to our listeners what are the gaps that were identified and what are its implications? Are there also other gaps which were not listed in the report?

Nithin Ramakrishnan [00:09:55] Thank you for a very important question. I would begin by saying that there were at least 3 committees who submitted reports to WHO on the functioning of member states and WHO during COVID-19 response. These committees identified several gaps in the text and its implementation. It must be noted that these are not something new. Some of the member States clearly knew this at the time of adopting IHR 2005, and some of the gaps were highlighted by previous IHR Review Committees established during the H1N1 pandemic and Ebola outbreaks. They highlighted certain gaps, the gaps relating to equitable access to health products, technologies and other innovations during emergencies; gaps related to the sharing of sample
pathogens and genetic sequence information along with benefits arising through the utilisation of such shared samples and information; the limited finance available under IHR 2005 for both capacity building and response and certain other technical gaps. IHR Review Committee during COVID-19 also very much critically identified these gaps. Yet their report was not explicit about the IHR 2005 blindness towards the divide between developed and developing countries. There is only one legal provision that takes into account the special status of developing countries in IHR 2005: Article 44, Paragraph 2. This provision requires WHO to mobilise financial resources or supporting developing countries in capacity building and maintenance. However, the Review Committee did not evaluate WHO’s performance specifically under this provision.

Vanita Mukherjee [00:11:39] As we are speaking, let's recall December 2021, where during a special session of the Health Assembly, governments agreed to draft and negotiate a convention or an agreement or an instrument to strengthen pandemic preparedness, prevention and response. These negotiations are ongoing right now and are being led by the Intergovernmental Negotiating Body to prepare a draft accord with the World Assembly in 2024. Now, why the need for a pandemic instrument or accord or treaty as it's very usually called when there is already an International Health Regulations 2005 or IHR 2005? Can you shed some light on that?

Nithin Ramakrishnan [00:12:25] Yes, of course. This is something which we will be very careful about from the beginning itself, because the proposal of a new treaty on pandemics was first mooted by the President of the European Commission, Mr. Charles Michael, at the Paris Peace Forum, number 2020. Later, the statement of the group of G7 leaders on 19th February 2021 called for exploring a global health treaty, while the EU Council went further by voicing its commitment to work on this particular treaty under the framework of WHO. But I would still prefer to refer this as a pandemic instrument, not as a pandemic treaty, since there is still a pending decision whether the new instrument will be a convention or agreement under Article 19 of the Constitution of WHO, or whether it would be under Article 21 of the WTO Constitution, which makes it a regulatory instrument. And this would happen only through a domestic process which would be taken up in states, parliaments or other forums. After the World Health Assembly Special Session that happened in December 2021. We must also take into note that all states have come to an unanimous decision that there is a need to develop such a new instrument. The Working Group on Amendments to the International Health Regulations is also doing the work parallel to the Intergovernmental Negotiating Body, which is trying to develop this new pandemic instrument. I would say the attempt of the EU, the US and other developed countries is to argue issues associated with equity, especially equitable access to health products such as vaccines has no place in IHR 2005. They want to park many of these issues relating to equitable access into the new pandemic instrument and at the same time they continue to dilute its provisions in the new instrument, which, according to them, cannot contain nothing more than sanitary procedures. Fortunately, developing countries have clearly opposed to these arguments and have shown them why IHR 2005 is not just about sanitary procedures. They also have explained how the scope of the new pandemic instrument differs from IHR 2005, showcasing the need for equity in both instruments so that equity measures and health system strengthening should be addressed in IHR 2005 and the new instrument should operate as a specialised instrument addressing the specialised cases of pandemic scale health emergencies, which would require higher standards of equity provisions and international coordination by pandemic scale emergencies. This particular new instrument
could be adopted under Article 57 of IHR 2005 as a complementing instrument or a supplementing instrument to IHR 2005. This is important because the way current negotiations treat these two instruments is prone to fragment both the international health work in a way the Global North is very keenly interested, I would say in this compartmentalising. Perhaps they believe fragmentation is good for them to escape obligations, whereas developing countries have significantly identified the need for complementarity between these two instruments. We, as civil societies, should be really particular to this approach and call out the ingenious attempts by developed countries to limit equity only to worldwide diseases outbreaks, such as COVID-19. Because of this, provisions on access to medicines in the new instruments would leave developing countries and their people neglected, even when the diseases are endemic to them. You can take the example of smallpox vaccines, which have been available for decades and which could have been repurposed for the MPox virus years ago but this was not done until developed country populations started getting affected in 2022. So, this is the kind of difference of scope between a pandemic instrument and a public health emergency of international concern.

Vanita Mukherjee [00:16:31] What are the major amendment proposals to the IHR 2005? Can you share some of the proposals put forward by developing countries and the response to them by the developed countries?

Nithin Ramakrishnan [00:16:43] Yes. I’m more than happy to take some time to explain the developing countries proposals which emerged out of their learnings from COVID-19 experience. And I think it’s very important for all of us to know about this and to bring this more into the public domain. There are several such important proposals. I’m only highlighting a few of them. Firstly, is the proposal to incorporate the health systems approach into the capacity building under the purview of IHR 2005. You may remember my first response to the question regarding IHR and how it is functioning that the whole law or the whole text and its implementation is shifted towards surveillance and reporting to WHO, not that much in terms of building response capacities or coordinating a public health response to public health emergencies. One of the reasons could be, as we mentioned, the colonial baggage. But the proposal from the developing countries is to clearly shift this focus and try to bring some change in this particular approach, taking time to actually look at it in a very systematic manner. The proposal is to move away from the kind of vertical approach the IHR is doing towards health systems capacity building, which is like focusing only on emergency capacities and forgetting about the basic health infrastructure which is required by countries. They would firstly prioritise health systems such as primary health care capacities or hospital care capacities and try to take international assistance on the basis of common responsibilities from developed countries in developing countries and invest in these capacities as well because all this is important for a response to health emergencies which are of international concern. The second important proposal is to establish a financial mechanism to achieve the above-said capacity building. The relevance of this proposal comes from the very fact that the World Bank Fund, which we all know, is not actually focusing on the priorities of the developing countries, that is primary healthcare and hospital care facilities. The focus is more again on surveillance and response capacity. I am using the world again, because if you look at the current levels of scores of states in achieving these capacities which are mentioned in IHR 2005, you would see most of the countries are almost doing well when it comes to laboratories and surveillance capacities, but they are lagging behind in many of the response capacities, including in infection and prevention control.
capacities. This fund, therefore, is clearly not following the WHO understandings and is clearly not accountable to WHO member states. So that is a building up a financial institutional mechanism within WHO to fund capacity building, as well as prevention and response activities. Thirdly, I would like to speak about the most important proposal by developing countries, that is the proposal for addressing the issues associated with equitable access to health products and technologies. Africa Group and another country, Bangladesh, have come with strong language on equitable access. So there are countries who have proposed amendments in this regard. Bangladesh and Africa Group have focussed on giving centrality to WHO by giving a mandate to WHO on assessing availability and affordability of health products during health emergencies, and also to figure out that there could be a potential shortage. If there is a potential shortage, then WHO is further mandated to come up with recommendations, including in an allocation plan or mechanism. This allocation plan needs to be followed by member states. This plan would not only articulate procurement and supply of health products or promote diversified production into developing countries, and these are envisaged by making changes in their domestic intellectual property laws, as well as altering the kind of conditions states would impose while they publicly fund research and development of medical products within the territories. These are not the only obligations. There is also other obligations such as to share critical information such as supply chain mapping or how to share know-how regarding the production of health products. Further, the proposal on Article 13A also obligates states to ensure that the private sector complies with the recommendations from WHO. I would say this is the most important proposal. Finally, the last one which I would like to highlight about developing countries proposals is actually a counterproposal to the US proposal, which sought to include sharing of genetic sequence data of pathogens within the health information that needs to be shared during public health emergencies. According to the Convention on Biological Diversity in the Nagoya Protocol, when you provide access to pathogens, its sequence information, you're actually entitled to get back fair and equitable benefits such as health products or technologies. We all know that vaccine is produced out of what we call as inaginated pathogen. It's produced using its sequence information, but there was nothing in the US proposal in terms of sharing back these vaccines or knowledge about vaccines or even platforms and technologies to produce these vaccines. All this could be considered as benefit sharing on a fair and equitable basis. What Africa Group has done, it very clearly pointed out that you know we can discuss about obligation to share genetic sequence information or data, but they said that that can happen only on the development of a benefit sharing mechanism, which would allow then countries to share not only pathogens and sequence information, but also benefits arising from that.

Vanita Mukherjee [00:22:10] There is much to reflect on and what strikes one is the proposals from developing countries in the IHR 2005, countries from Africa and Bangladesh. And I think some of the lessons they learned from COVID-19 have really helped them craft some of these proposals. There's so much to reflect not only in terms of a need for a fair and equitable mechanism, the whole emphasis on equity coming up with very creative solutions, including thinking about countries legal mechanisms and how they can be changed to allow access to some of these poorer countries to diagnostics, vaccines and therapeutics. Now, all this is happening in the rarefied space of the World Health Organisation, which is far from issues that feminist movements and other social movements deal with. Why should we all, social movement, civil society organisations, feminist movements keep track of or even engage with these two processes as they're being discussed? How is this going to affect all of us?
Nithin Ramakrishnan [00:23:16] I would say, in international health law, what is basically required at this point of time is an imagination of what is required at the ground level. We need medicines, vaccines, hospital beds and a better number of doctor patient ratio. So perhaps these ideas are what can actually capture the common mind and can actually change IHR 2005. And it's only the civil society organisations and social movements and feminist movements like us who can actually raise voice about them. So we have to really speak about this and put it into the minds and the imagination of the negotiators, as well as the policymakers that think about what is happening on the ground – the need for decolonising this particular law forever.

Vanita Mukherjee [00:24:01] I think you've thrown a lot of light on several issues as laws and legal obligations are being discussed, revised, framed to deal with global health governance issues beyond surveillance, and to move it towards more of equity, health systems change, financial mechanism and most important of all, the call for benefit sharing and accountability. But most importantly, how these processes evolve and what are the ways in which the developing country and the Global South can stand on their ground and negotiate with the Global North will also decide on who has access to medicine and how this will always remain critical. Thank you so much.

Nithin Ramakrishnan [00:24:45] Thank you.

Vanita Mukherjee [00:24:50] The Feminists for a People's Vaccine podcast is produced by DAWN - Development Alternatives with Women for a New Era and TWN - the Third World Network. Today's episode was edited by Alice Furtado and engineered by Ernesto Sena. Thank you for joining us today. I'm Vanita Nayak Mukherjee. See you on the next episode.