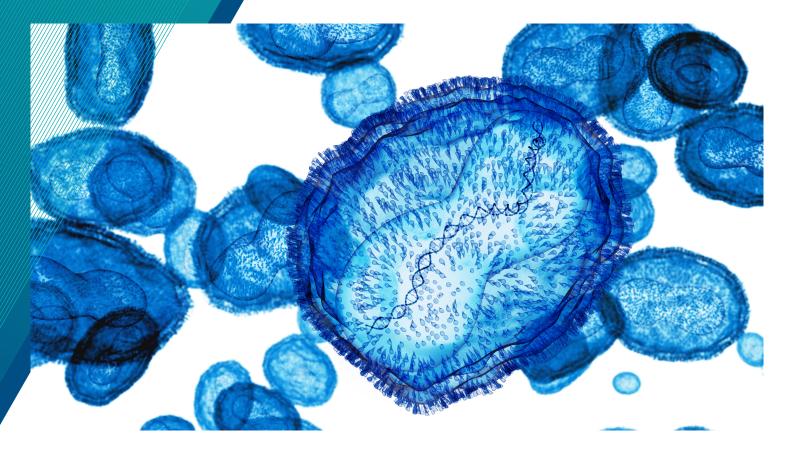
Facts & Findings





Have we learnt anything from the Corona Pandemic?

The Monkeypox as the next Stress Test for more Global Distributive Justice Moritz Fink

- Following recent experiences of the Corona pandemic, the Monkeypox once again presents us with the global susceptibility to infectious diseases.
- The International Health Regulations (IHR) for overcoming cross-border health threats are neither effective enough nor do they achieve the necessary impact. The terms "pandemic" and "epidemic" do not appear in the IHR.
- There continues to be a need for reform following experiences from the Corona pandemic and the Monkeypox virus regarding a more effective pandemic instrument.
- Mistakes of the (global) Corona pandemic management (vaccine procurement and distribution, stockpiling, access to diagnostics) are also being repeated with the Monkeypox.
- This is reason enough to think about continuing the ACT-Accelerator and COVAX, so as to achieve more distributive justice and maintain close collaboration between global health actors.

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1. Monkeypox classified as an International Health Emergency

On 23 July 2022, the WHO Director-General Dr. Tedros Adhanom Ghebreyesus declared the Monkeypox outbreak to be "a global health emergency of international concern" (PHEIC). According to Dr. Tedros "we are [...] dealing with an outbreak that has rapidly spread across the world through new transmission routes of which we still know too little, and which meets the criteria of the International Health Regulations (IHR)".¹ At the start of October, there were more than 69,000 known cases of Monkeypox in 107 countries, of which the vast majority (100) had never previously recorded an infection. As of 4 October 2022, the Robert-Koch-Institute (RKI) registered a total of slightly more than 3,600 confirmed cases in Germany.² From a global perspective, however, the number of new cases of Monkeypox registered weekly with the World Health Organisation has declined since mid-August. This is mainly due to a drop in the number of cases in Europe.

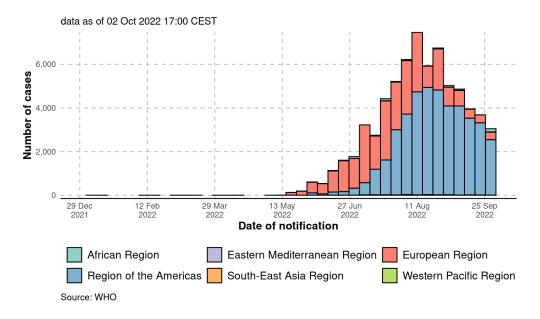


Figure 1: Monkeypox, global trend according to WHO regions

source: WHO, 5 October 2022

The numbers are decreasing in Germany, too: Since early September, some 50 new cases have been reported to the RKI each week. Since October, the numbers have only been in the low double-digit or single-digit range.³

In June, the WHO Emergency Committee for the Assessment of an International Health Emergency convened, but decided against declaring the highest alert level. Dr. Tedros agreed with this assessment at the time. Scarcely a month later, the Director-General reconvened the 15-member expert committee, in order to consult further in light of the dynamically evolving Monkeypox disease. Even though only six members of the committee voted in favour of the definition as a health emergency of international concern, Dr. Tedros ultimately decided to classify the Monkeypox as such from now on.

According to the WHO statutes, a health emergency of international concern (*PHEIC*)⁵ exists when there are "sudden, unusual and unexpected" health problems, which can spread to other countries. The ability of the WHO to declare a PHEIC is an essential part of the IHR, calling on member states to take immediate action. The most well-known example of a health emergency of international concern is Covid-19 (since 2020), however, this designation also applied to Ebola (2014, 2019), Zika (2016) and H1N1 (2014). Polio has been classified as PHEIC since 2014.

Definition of a health emergency of international concern.

Dr. Tedros' decision is unprecedented to some extent, given that no Director-General, since the inception of the IHR, had previously declared an international health emergency when the expert committee was divided. While this competence is covered by the mandate of the WHO Directorate-General within the framework of the IHR, observers agree that it conveyed the WHO's capacity and willingness to make decisions. Especially after strong criticism levelled against the WHO leadership when the Corona pandemic 2020 started ("too hesitant, too indecisive"), the WHO evidently wanted to avoid such an accusation again, that it was either acting too late or not appropriate to the situation.

2. International Health Emergency equates to a Pandemic?

Although a PHEIC declaration is not accompanied by far-reaching commitments, there are a number of specific recommendations that countries can comply with in their fields of responsibility; first and foremost, to counteract the occurrence of infection, but also, for instance, to enable improved access to vaccines (also globally). This includes assessing their own, country-specific risk, the creation of necessary public health measures (diagnostics, treatments, contact tracing, preparedness of hospitals) and participating in the international crisis response. The latter consists of vaccine supply and distribution as well as help for regions and countries particularly affected by the outbreak. In its recommendations for dealing with the Monkeypox, the WHO classified four country groups with regard to the underlying occurrence of infection, transmission routes and test capacities. All advice to the countries so far is "preliminary" and not legally binding; it merely addresses the voluntary willingness of governments to coordinate more closely with other countries and particularly with the WHO. The WHO uses its limited powers to warn the world against a health threat and to provide countries with recommendations for action.

That is why a PHEIC declaration is in principle just a global warning and a call to action. At the same time, an international health emergency does not release new funds, nor initiate new funding rounds nor does it compel countries to commit to higher amounts. The mandate and competences of the WHO remain unaffected. Ideally, the WHO itself could react flexibly with its funds in case of emergency and shift them in a targeted manner; after

Follow-up mechanisms of an international health emergency: few obligations.

all, this is the core of the organisation's sustainable financing agreement adopted at the last World Health Assembly in May 2022.⁷

Moreover, determining a PHEIC is not tantamount to declaring a pandemic.⁸ An international health emergency should already be proclaimed prior to a pandemic, so as to avert it on time with accompanying measures. From a legal perspective, there is not (yet) such a thing as a pandemic-declaration at the global level. The IHR neither contains the term "pandemic" nor "epidemic", even though, especially in light of the spatial proximity between humans and animals and advancing climate change, it is likely or relatively certain that further zoonoses with pandemic potential will occur in future.⁹ The two-day WHO meeting *Research & Development Blueprint for Epidemics* identified antibiotic-resistant germs, influenza and Crimean-Congo haemorrhagic fever in particular as possible pathogens "X" with pandemic potential.¹⁰

International Health Regulations do not include the term pandemic.

In sum, there are already clear indications of the urgent need for reform of the global health architecture in the area of crisis response. The next section demonstrates the extent in which specific experiences from the Corona pandemic and the *Covid-19 Vaccines Global Access-Initiative* (COVAX) for more distributive justice (medication, equipment, tests) have now taken effect in dealing with Monkeypox.

3. Initial Mistakes from the Corona Pandemic are being repeated

Even though a PHEIC declaration to some extent obligates governments to coordinate their efforts so as to stop the spread of the virus, IHRs are not sufficient for early containment of an international health emergency. Deficits in the international crisis response became blatantly obvious in light of the Corona pandemic, and are now being repeated in the access and availability of vaccines against Monkeypox. Existing stock of Monkeypox medication and vaccines have already been used up by high-income countries, or the countries continue to secure the quota of vaccines available on the market.¹¹ At 110 US Dollars per vaccine, poorer countries in particular are excluded. The United States previously controlled the majority of the vaccines originally developed for smallpox, as part of its biological weapons strategy following the terrorist attacks of 11 September 2001.

Monkeypox as the first stress test for more distributive justice.

Current stocks fall well below what is needed to supply particularly risk-prone groups. To this end, the USA and Great Britain have decided to "stretch" their existing vaccines so that they are available to a larger proportion of the population. The European Medicines Agency (EMA) also issued an approval for this measure, according to which five times more people can now be vaccinated with the same vaccine amount.

The unequal distribution of vaccines, medication as well as diagnostic appliances is most evident when looking at Africa. To date (as of 12 September 2022), the African continent has not received any vaccine batches or antiviral treatments against the Monkeypox virus, as communicated by representatives of the African Centres for Disease Control and Prevention (African CDC). And yet the disease is endemic in many countries in Africa and often more dangerous than elsewhere, which speaks in favour of prioritising the vaccine distribution to Africa from a medical-scientific point of view.¹³ What is more, health officials on the continent bemoaned the fact that more test kits are generally needed to improve appropriate emergency measures and to even be able to initiate them in the first place. In mid-September 2022, the WHO Africa region merely received 39.000 tests.¹⁴ A similar picture emerges on the South American continent: Neither the antiviral drug nor the vaccine administered in the United States and Europe against Monkeypox, are available in Peru, for instance, which is also severely affected by the outbreak. In neighbouring Brazil, where according to data from

Unequal distribution of available material (vaccines and tests).

the World Health Organisation almost ten per cent of the global Monkeypox cases occurred, deliveries have thus far failed to materialise. 15

The slow response and lack of support for African countries thus does not reflect the urgency called for in the WHO's declaration on the international health emergency for Monkeypox, according to the Director of the African CDC. "We need a coordinated international response with greater efforts to support the control of Monkeypox as an outbreak of international concern", concludes the Director. ¹⁶ Despite proclaiming a health emergency, the WHO lacks clear guidelines for a strategy on how vaccines, treatments and tests can be provided to the countries that need them", said James Krellenstein, Founder of the PrEp4All alliance. "It seems unwise to declare an emergency without saying anything about the means by which to respond."¹⁷

4. International Health Emergency also means joint Responsibility

The inevitable question that arises is the division of responsibilities in a global crisis response to a health emergency. Global health is synonymous with a multi-level system with the WHO and its regional offices (for example WHO Europe) at the top. Added to this are the various disease agencies such as the African CDC and national focal points, as well as national governments. Among them are various sub-national and regional institutes and health authorities (such as the Public Health Services).

With the example of Cameroon, we can see that the disease has received little political attention even in countries where Monkeypox has traditionally circulated and been increasingly present for a long time. Thus, in recent years there has been no clear prioritisation when combating Monkeypox in this country; what is more, clear surveillance plans have not been called for or drawn up. Funding requests for procuring diagnostics and medication have not occurred.¹⁸ Historically, mainly inhabitants in the more rural regions of Cameroon became infected with Monkeypox, who, in any case, have fewer resources, less political participation and are thus often marginalised. That is why there was a lack of attention here and downstream reporting chains to warn the population and neighbouring countries.¹⁹

Hence, closely observing local sites of outbreak is essential for the global crisis response. Ideally, countries should think about health globally and take the appropriate action, especially when a health crisis with pandemic potential is starting to emerge locally. Global solidarity in a pandemic is not only a humanitarian imperative, but also an important means of self-preservation. An early distribution of vaccines and medication to the endemic regions would be the right approach here. If this does not succeed, then in retrospect, at least a fairer distribution and equal access to vaccines would need to be ensured.

Health invariably has a global component too.

5. Summary I: Limited Effect of a PHEIC Lever

The WHO is responsible for declaring a PHEIC, sounding the alarm and holding countries responsible if the response is not coordinated or adequate enough to the threat. In doing so, the WHO sheds light onto and criticises countries for stockpiling vaccines. Within its mandate, however, the WHO cannot force countries to give up vaccines or assign patent rights.

In future, it would be beneficial if the WHO, after the announcement of a PHEIC, was to immediately have a plan and provide guidance about what is expected for implementing the international response, which of course includes the execution of an equitable distribution

mechanism. Plus, there is no survey for evaluating the effectiveness of a PHEIC that would help to analyse and improve the importance of the lever. In any case, a PHEIC generates increased media attention and creates scope for measures to contain the health emergency.

The WHO therefore uses its existing, limited powers to warn the world against a health threat and to provide countries with appropriate recommendations for action.

6. Summary II: Reforms initiated in the Global Health Architecture

A more binding (distribution) mechanism²⁰, which would come into effect upon declaration of a pandemic or an international health emergency, would therefore be a much-needed step. To this end, two (different) instruments are currently being discussed among WHO member states: Both a revision of the existing International Health Regulations and the idea of a completely new pandemic treaty.

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Need for reform in

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global health. Revision

At the World Health Assembly (WHA) in May 2022, member states agreed to initiate a reform of the IHR and appoint a working group. The WHO member states now had time until 30 September 2022 to provide their own reform proposals to the working group. A reform package should be ready for adoption at the 77th WHA in May 2024 at the earliest. The deadline for implementing the revised IHR will be shortened to twelve months following entry into force; hence, the new regulations would apply as of May 2025. Nevertheless, it soon became clear at the WHA and in some subsequent meetings that there are major differences between member states regarding the scope and content of reforms to some extent.

Another approach is now being pursued by the *Intergovernmental Negotiating Body* (INB), a body at national governmental level, for drawing up a convention, an agreement or other international instrument to strengthen pandemic prevention, preparedness, and response.²¹ As mentioned, this aims to develop a completely new toolbox for the international crisis response in health emergencies, even if it is only applied "complementary" to the existing IHR. Here, too, there is no lack of ideas and proposals as well as differences of opinion about what should be addressed in the so-called "pandemic treaty".²²

Since the vulnerability to (global) infectious diseases is becoming increasingly clear, that is likely to attract attention to the pandemic treaty negotiations – even if eminently important points such as access to sites of outbreak and data exchange will probably not be affected by this.²³ Just as the feared encroachments on national sovereignty propounded by China and Russia are likely to decisively impede negotiations in future, too. There is not expected to be an outcome of these negotiations until the World Health Assembly in 2024 at the earliest.

Reform efforts initiated as a response to the Corona pandemic are therefore important for future health emergencies of international concern. If an agreement had already been reached, then, for example, a mechanism could have become effective following the declaration of a PHEIC, as was recently the case with Monkeypox. Then – as was hoped – a more inclusive, equal distribution of the limited resources (medication, vaccines) would have been possible.

Until a pandemic treaty is negotiated or the IHR is revised, priority is now being directed to the Monkeypox outbreak and the still very present Corona pandemic. The former might once again highlight the deficient crisis response at the international level regarding stockpiling tendencies, and thus strengthen current negotiations.

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7. Revisiting the Model of ACT-A for creating a Distribution Mechanism – Integration into future Pandemic Instruments?

Still, the Corona pandemic gave rise to an underestimated instrument in the form of the global COVAX initiative, which strives for an equitable distribution mechanism of vaccines and appeals to the moral responsibility of countries. After all, only through COVAX, as a vaccination platform of the global coordination mechanism *Access to Covid-19 Tools Accelerator* (ACT-A)²⁴ did some countries have the opportunity to receive vaccines in the first place. In particular, the ACT-A also sheds light on the contributions and donations of individual countries to the global initiative. This reporting tool tends to hold countries to account and their contribution can be accurately estimated. It therefore becomes more difficult for countries to not participate in an international solidarity project ("naming and shaming").

ACT-Accelerator offers potential for international crisis response.

The continuation of the international vaccine platform COVAX as part of the ACT-A coordination mechanism certainly makes sense. Yet, it still cannot be foreseen whether a transitional mechanism for ACT-A will extend beyond autumn and the next months, or rather which elements of the initiative (for example research and development in diagnostics, regular meetings between global health organisations) should potentially be retained. Against the backdrop of a better positioned global health architecture with closer cooperation between partners, which currently come together every Thursday to coordinate their activities, it would also be worth considering reactivating the established structures under ACT-A, led by the WHO, in the event of a PHEIC. Based on the four pillars (Therapeutics, Diagnostics, Vaccines and Health System Connector), the global health actors such as UNITAID, FIND and Gavi, the Vaccine Alliance, can contribute in a tried and tested way and work together to provide poorer countries with diagnostics, protective equipment, medication, and vaccines.

The focus of the *Access to Covid-19 Tools Accelerator (ACT-A)*, as the name already suggests, on overcoming the Corona pandemic, entails the difficulty of securing funding for activities on an ongoing basis since the peak of the pandemic is already over, or appears to be.²⁵ The question of the fate and future of ACT-A is posed at a time when funding for the global fight against Corona is running out, and governments as well as major global health organisations are turning their attention to other health issues, including pandemic preparedness.²⁶ The best example for this is the establishment of the *financial intermediary fund (FIF) for pandemic prevention, preparedness, and response (PPR)* based at the World Bank and with technical support from the WHO. In particular, PPR capacities (zoonoses surveillance, laboratories, emergency communication, coordination and management) will be strengthened in low- and middle-income countries and critical gaps closed through investments and technical support at national, regional and global levels.²⁷ Specifically, an extension and development of local drug production could be achieved via the FIF.

8. Outlook

The idea of a more equitable (or more inclusive) access to vaccines and medication has not yet been taken into account by the World Bank's pandemic preparedness fund. Experiences from the Corona pandemic and the creation of ACT-A as an initiative for accelerating the development, production and equitable distribution of Covid-19 tests, treatment methods and vaccines do not therefore need to specifically apply to Corona, but can be understood as a blueprint for the global crisis response in a health emergency of international concern. This mechanism could well have been applied when dealing with the Monkeypox: Endemic regions where the virus has existed for a long time and where more deaths occur, could have been given preferential support. But as we know, there were and still are reports of

ACT-A structures as a blueprint for the global crisis response following declaration of a PHEIC. stockpiling tendencies for the few available pox vaccines and medications here as well, thus posing an obstacle to a more equitable global distribution. The global response to the Monkeypox therefore unequivocally shows that the declared debate on equity, especially after Corona, has not led to any improvements in terms of access and distribution.²⁸ An analysis of the global outbreak of Monkeypox consequently reveals a failed stress test for greater global distributive justice – the first following the start of the Corona pandemic and the COVAX initiative.

Incorporating a distribution mechanism that counteracts stockpiling tendencies of the Global North to some extent, would be therefore advisable in negotiations for drawing up a pandemic treaty and could be promoted relatively easily owing to existing structures and processes. Following the declaration of an international health emergency, a mechanism according to the ACT-A model could then take effect.

The inclusion of ACT-A experiences so as to prevent fragmentation in the health sector, could also become the subject of debate of the Global Action Plan (SDG 3) co-initiated by Germany; the revival of which has now come to the fore and is being requested by the Federal Ministry for Economic Cooperation and Development (BMZ) in the stakeholder dialogue. Following the overwhelmingly positive experiences of ACT-A, Germany could advocate for its continuation or even expansion (for instance, embedding structures in a new multilateral agreement). Ongoing funding for ACT-A would also be in the interest of Germany, which enjoys an excellent reputation in global health, sees itself as a staunch supporter of multilateral initiatives and consistently emphasises global solidarity.

Until then, the international community should be more proactive in their preparedness for a pandemic (forwarding thinking). The key question for those responsible – especially after recent experiences – should be: In what way are we prepared for a global outbreak of "pathogen X" today, and, particularly with this in mind, how can we provide a genuine global response?²⁹ Therefore, recent experiences of health emergencies (Covid-19, Monkeypox) have taught us to place far more emphasis on global distributive justice. In this context, the success of ACT-A as a coordination mechanism may well be reflected in considerations on the current reform effort. There should therefore at least be basic consensus (until conclusion of a potential agreement at the WHA 2024) on the extension of ACT-A beyond autumn 2022.³⁰

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- 3 Cf. Fn. 2
- Wientzek, Olaf et al.: Geneva Barometer, online at: https://www.kas.de/de/web/multilateraler-dialog-genf/laender-berichte/detail/-/content/genfer-grosswetterlage-15 (last accessed on 12/10/2022).
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- 16 Adpoju, Paul: Africa Has Not Received A Single Dose Of Monkeypox Vaccine Even Though Virus Is Endemic And Often More Deadly, in: *Health Policy Watch*, online at: https://healthpolicy-watch.news/africa-single-dose-monkey-pox-endemic/ (last accessed on 12/10/2022).
- 17 Cf. Fn. 11
- 18 Guzman, Javier: Pandemic Proof: Evaluating the Monkeypox Response (Podcast des Center for Global Development), online at: https://www.cgdev.org/blog/pandemic-proof-evaluating-monkeypox-response?utm_sour-ce=20220830&utm_medium=cgd_email&utm_campaign=cgd_weekly (last accessed on 12/10/2022).
- 19 Cf. Fn. 17.
- 20 Yet, binding does not inevitably mean that states will comply with it at all times.
- 21 Negotiations on the reform of the IHR are taking place at the same time. There was an agreement to this end at the last World Health Assembly in May 2022. Cf. Fn. 4.
- 22 To the surprise of many, representatives of the members states were recently able to agree on a legally binding

- framework. Cf. WHO Communication: Outcomes of the first round of public hearings, online at: https://apps.who.int/gb/inb/pdf files/inb1/A_INB1_10-en.pdf (last accessed on 12/10/2022); Fletcher, Elain Ruth et. al.: Sharing Genomic Data In Exchange For ,Benefits' And One Health: Emerging Hot Spots In Pandemic Accord, in: Health Policy Watch, online at: https://healthpolicy-watch.news/access-genomics-one-health-pandemic-accord/, (last accessed on 12/10/2022).
- 23 However, this raises the question as to whether the treaty will be watered down and become tantamount to a toothless tiger. It is quite possible that a coalition of the willing will proceed here and launch a more rigorous pandemic instrument that countries can join (opt in). While negotiations on the IHR reform could of course benefit from this as well; for instance, if countries (after experiences from the Corona pandemic and with the Monkeypox virus) submit their own proposals to the working group. Further points of contention are issues pertaining to patent rights for example (cf. debates on TRIPS waiver).
- 24 Access to COVID-19 Tools (ACT): Global initiative to accelerate the development, production and equitable distribution of Covid19 tests, treatment methods and vaccines. ACT-A is based on four pillars (Therapeutics, Diagnostics, Vaccines and Health Systems Connector). Cf.: The Access to COVID-19 Tools (ACT) Accelerator, online at: The Access to COVID-19 Tools (ACT) Accelerator (who.int) (last accessed on 12/10/2022).
- 25 Banco, Erin et al: World's Covid vaccine, drugs equity program set to wind down this fall, in: *POLITICO*, online: World's Covid vaccine, drugs equity program set to wind down this fall POLITICO (last accessed on 12/10/2022).
- 26 For example, the EU is planning a global health strategy.
- 27 WHO Communication: New fund for pandemic prevention, preparedness and response formally established, online at: https://www.who.int/news/item/09-09-2022-new-fund-for-pandemic-prevention--preparedness-and-response-formally-established (last accessed on 12/10/2022).
- 28 Even though Corona and the Monkeypox, of course, cannot be compared with regard to incidences and mortality.
- 29 Further reading: Sachs, Jeffrey D. et al: The Lancet Commission on lessons for the future from the COVID-19 pandemic, online at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01585-9/fulltext (last accessed on 12/10/2022).
- 30 The exact future/transition of the ACT Accelerator is subject to speculation and still unclear. In the following interview, Dr Bruce Aylward from the WHO Leadership Team provides insights into a potential restructuring of the ACT-A. https://www.devex.com/news/act-accelerator-has-to-change-who-s-bruce-aylward-lays-out-plans-104073 (last accessed on 12/10/2022).

Imprint

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