International law reform for One Health notifications

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Epidemic risk assessment and response relies on rapid information sharing. Using examples from the past decade, we discuss the limitations of the present system for outbreak notifications, which suffers from ambiguous obligations, fragile incentives, and an overly narrow focus on human outbreaks. We examine existing international legal frameworks, and provide clarity on what a successful One Health approach to proposed international law reforms—including a pandemic treaty and amendments to the International Health Regulations—would require. In particular, we focus on how a treaty would provide opportunities to simultaneously expand reporting obligations, accelerate the sharing of scientific discoveries, and strengthen existing legal frameworks, all while addressing the most complex issues that global health governance currently faces.

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Introduction

Disease outbreaks can become pandemics when there are delays in, or even complete failures to implement, appropriate interventions to stop transmission. A report by the Independent Panel for Pandemic Preparedness and Response established an exhaustive chronology of the first 3 months of the COVID-19 pandemic and found that delays in notifications, information sharing, and international responses to alerts, including the declaration of a Public Health Emergency of International Concern (PHEIC), had global repercussions.[1] Failures during the COVID-19 pandemic have garnered global attention and led to scrutiny of compliance with obligations under the International Health Regulations (IHR) 2005,[2] but these failures are only one instance of a much broader problem relating to outbreak reporting and information sharing.

The discovery and publication of a coronavirus outbreak

Despite hopes that the COVID-19 pandemic would compel faster action to stop future coronavirus outbreaks, the speed at which another coronavirus discovery from the past 5 years unfolded suggests otherwise. Independently, in 2021, two research groups reported that alphacoronavirus 1—a species complex that includes feline, canine, and porcine coronaviruses—was the eighth coronavirus to make the jump into humans. The discovery was foreshadowed by a 2014 study that screened samples collected by the Arkansas Department of Health, USA, from patients with influenza-like illness in 2010, and found three cases of a feline coronavirus-like virus.[3] Although the study reported plans to attempt viral isolation and further research, no follow-up has yet been published, and as of 2014, alphacoronavirus 1 was still widely considered to be limited to animals.

In 2017 in Malaysia, swabs were collected from patients with respiratory infection in a hospital in Sarawak, and screened for common respiratory viruses. The results were published by early 2019.[4] A year later, a second paper was published that made use of a new assay to analyse these same samples with more granularity,[5] and reported that four cases tested positive for a recombinant canine coronavirus. This 2020 study was followed by another, published in May, 2021, reporting the isolation of canine coronavirus HuPn-2018 (CCoV HuPn-2018) and the results of a field epidemiological study that included assessing contact with household pets and wild animals.[6]

Halfway around the world, the same scientific discovery unfolded in Haiti. In 2017, several doctors returned to the USA after a Zika virus outbreak response mission, presenting with febrile illness. Samples tested negative for Zika virus, but cell line experiments and sequencing indicated the presence of an unknown coronavirus with a high identity to porcine coronavirus. This discovery went unreported for half a decade until, by the scientists' account, the Malaysia study[6] gave them a new lead in 2021, resulting in the discovery and announcement of another zoonotic recombinant canine coronavirus.[7] As an epilogue, the same research team reported in *Nature* a few weeks later that earlier febrile illness samples collected in Haiti in 2014–15 had revealed independent spillover of porcine deltacoronavirus, the ninth coronavirus—and the first deltacoronavirus—to infect humans.[8]

These studies tell very different stories about how the same scientific discovery can unfold. In the Malaysian example, routine syndromic surveillance led to incremental discoveries that were refined and sequentially published within roughly a year. In the Haiti–USA example, the same unknown virus infected several health-care workers, who travelled across international borders; the virus was identified as an unknown coronavirus, with no other reported attempts at containment. The discovery was unreported to the public, and potentially (in the absence of statements otherwise) to other countries and WHO for half a decade. If the outbreak was reported to any national or international body, that information was never transparently shared with the public. At the time all samples were collected, the world was aware of the potential for novel coronaviruses to cause serious illness in humans: epidemics of SARS-CoV and MERS-CoV had already displaced historical assumptions about coronaviruses' mildness. In the time it took to update scientific knowledge about the canine coronavirus, the world would face a coronavirus pandemic that has caused 15 million deaths to date.

The world's experiences with these novel coronaviruses are distinguished only by chance in the viral genetic lottery. Alphacoronaviruses are often treated as a lesser pandemic risk than betacoronaviruses, given that infections with human coronavirus 229E and NL63, both alphacoronaviruses, are fairly mild in humans, but it is possible that novel alphacoronaviruses might emerge with greater severity than they have done previously. Notably, CCoV-HuPn-2018 was first detected in patients hospitalised with pneumonia, and symptoms are largely undescribed in the Haiti outbreak beyond febrile illness. Although little is known about human-to-human transmission in both canine coronavirus outbreaks,[9] the global circulation of 229E and NL63 highlights that alphacoronaviruses have (infrequently) emerged and spread worldwide previously in human history, and could plausibly do so again.

Had the canine coronavirus outbreak in Haiti and the USA been the start of such an event, the historical evidence available to us suggests that notification systems would have failed to sound the alarm any more effectively than during the early days of the COVID-19 pandemic. As evidence of capacity to infect humans accumulates,[9] any discovery of additional human cases is likely to be shared more rapidly by scientists. States might therefore be more likely to notify WHO, but given that the risks of onward transmission and severe presentation of alphacoronavirus infection are still widely seen as low, there are no guarantees that states would take this action. Moreover, the global prevalence of pre-emergence alphacoronavirus 1 strains with zoonotic potential is unknown. If One Health surveillance systems identify viral sequences in animals that suggest a potential risk of emergence in new human populations, existing systems are unlikely to result in rapid sharing of those discoveries. These kinds of challenges exemplify the broader question of how notification systems will handle the next coronavirus: in the future, without a syndromic event of similar size to the COVID-19 case cluster initially detected in Wuhan, China, it is not guaranteed that a human case of a novel coronavirus, or even specifically a severe acute respiratory syndrome (SARS)-like or Middle East respiratory syndrome (MERS)-like virus, would be taken more seriously than canine coronavirus was.

The current global system for outbreak risk assessment and notifications, including the current international legal obligations and scientific norms, increases the likelihood of a future outbreak becoming another pandemic. Without thoughtful amendments to the existing notification regime that consider these risks, we gamble global health security on not just the success of local outbreak investigations, but also domestic reporting laws and the accountability, incentives, and efficiency of individual scientists and academic publishing.

How outbreaks are reported today

A number of international legal systems are in place to ensure information sharing with respect to disease outbreaks. However, these systems are fragmented across international organisations that work under different thematic mandates.

Outbreaks in humans

When SARS emerged in 2002, China was not legally obligated to report the outbreak under existing international law. At that point in time, novel diseases were not captured by the primary multilateral treaty, IHR, which instead listed a set of specific notifiable diseases: namely cholera, yellow fever, and plague, reflecting the outdated and colonial histories of the IHR. Despite the legal gap, there was broad recognition that an expected norm to notify potential international health threats existed and should be reflected in the IHR. Motivated by this experience, WHO member states adopted the revised IHR in 2005, establishing an all-hazards approach that encompasses biological, chemical, and radiological threats to health. Under the IHR, states parties are required to notify WHO of outbreaks under specific circumstances; these circumstances determine whether WHO is required to keep the outbreak confidential or report it directly to the press or through WHO's Disease Outbreak News (DON), its formal outlet for publicly reporting outbreaks.

Under Article 6 of the IHR, member states are required to notify WHO of extraordinary events that could constitute a cross-border threat to public health and might require an internationally coordinated response. To assist states in deciding whether an event meets these Article 6 criteria and must be notified to WHO, the IHR include a decision algorithm instrument in Annex 2. Under the algorithm, only events that involve a case of smallpox, poliomyelitis caused by wild-type poliovirus, novel human influenza, or SARS are immediately notifiable as they are deemed always unusual or unexpected, with potential for a serious public health impact. In addition to these four diseases, the decision instrument explicitly names seven further viral diseases and two bacterial diseases. However, along with "any event of potential international public health concern, including those of unknown causes and sources",[10] states must first use the algorithm to determine whether notification is required. For an event to be notifiable to WHO, it must satisfy at least two of four risk criteria ("Is the public health impact of the event serious?"; "Is the event unusual or unexpected?"; "Is there a significant risk of international spread?"; "Is there a significant risk of international travel or trade restrictions?").[10] This evaluation is subjective, and a 2009 exercise found that National IHR Focal Points only achieved a 78% consensus on hypothetical evaluations, with the greatest level of disagreement in deliberately ambiguous cases, thus indicating that in a real-world crisis, state responses could be unreliable for predicting risk.[11] Under Article 9 of the IHR, WHO is empowered to receive reports from non-state sources, but this type of reporting is limited to active events for the purpose of outbreak response, and it

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requires WHO to verify the report with the affected member state.

Outbreaks in animals

The World Organisation for Animal Health (WOAH) maintains its own independent notification system for disease outbreaks in animals. Under the OIE's founding documents (the International Agreement for the creation of the WOAH and its Organic Statutes), WOAH member countries have a general notification obligation for particular diseases. The scope of this obligation is further detailed under sets of standards known as the WOAH's Terrestrial and Aquatic Animal Health Codes. Generally, the standards under these codes set out various circumstances for notifications involving listed diseases, including the occurrence of a disease or recurrence of an eradicated disease in a new region or setting; the occurrence of novel or eradicated strains; and sudden changes in the (known) host range, virulence, incidence, or burden of the disease. Like the WHO DON, OIE notifications are usually reported publicly through the World Animal Health Information System. Although the codes are not themselves legally binding treaties, the International Agreement for the creation of the OIE is, and both codes are recognised as international standards under the World Trade Organization's (WTO's) legally binding Sanitary and Phytosanitary Agreement, applicable for WTO members, meaning that members applying the standards can presume they are complying with their WTO obligations.

The 117 notifiable diseases heavily favour those with a substantial impact on livestock over wildlife diseases, which are under-represented in many notable cases. For example, of the two panzootics within the past 30 years that have posed serious threats to wildlife conservation, chytridiomycosis of amphibians is listed, but white-nose syndrome of bats is not. The list is also poorly tailored to preventing zoonotic emergence: for example, MERS-CoV infections in camels are included, but not any other coronaviruses; Nipah virus is included, but the closely related Hendra virus is not; and neither Ebola virus nor Marburg virus are listed, despite some evidence of domestic animal infections as sentinels of human outbreaks.[12] Discoveries with public health importance could easily slip through these cracks: for example, a 2021 publication was the first to report the discovery of a novel Hendra virus variant that might not be detected by normal testing.[13] The Hendra virus g2 genotype was identified from bat samples collected in 2013, sequenced in 2016, and published alongside 9 years of genetic surveillance.[14]

Limitations

Existing frameworks are conspicuously mismatched with the modern scientific understanding of disease emergence, which indicates a need to adopt a One Health approach to notifications—ie, one that recognises the interconnection among human, animal, and environmental health. The present system mostly compels notifications during human health emergencies or outbreaks of important livestock pathogens, but an integrated system would recognise that emerging zoonotic threats begin in wildlife and livestock,[15] with some of the greatest opportunities for action before a full-blown emergency begins. Major epidemics are often preceded by dead-end spillover and stuttering chain outbreaks (ie, viral chatter[16]), which are indicative of both stochastic outbreak trajectories and latent variation in transmissibility; more often than not, these warning signs are noted retrospectively after a large outbreak begins.[17,18] Smaller outbreaks, even of conspicuous diseases, such as haemorrhagic fevers,[19,20] often go undetected by syndromic surveillance, but serological data can fill those gaps, just as evidence of antibodies to SARS-like viruses in southern China preceded the COVID-19 pandemic.[21,22] Because antibodies are less time-specific than active infections, serological data in particular are often shared with the world less urgently than outbreak data. For example, before the Kivu Ebola virus disease outbreak in the Democratic Republic of the Congo (July, 2018, to June, 2020), a team of researchers found 10% Ebola virus seroprevalence in samples collected from the region from May, 2017, to April, 2018, indicating a risk of outbreaks in the area; the results were published in November, 2020.[23]

Animal surveillance can also indicate that particular populations or areas face spillover risk, especially if viruses of concern are being detected in animals (and serological evidence indicates human exposure) at high-risk interfaces such as wildlife markets and supply chains,[24–26] or in domesticated animals.[13,27–29] Thanks to methodological advances in experimental virology[30,31] and computational biology,[12,32,33] some wildlife viruses can even be identified as potential threats before the first known case of human infection, and gaps in countermeasures can also be assessed.[30,34] These surprisingly simple methods rely on the sharing of viral genomic sequence data, which—once an outbreak is underway—can be used to reconstruct and track human-to-animal pathogen spillback, and monitor for the evolution of new variants of concern in wildlife reservoirs.[35,36]

Almost all of these lines of evidence fall outside the narrow criteria that exist for emergency notifications, but each constitutes an important part of how One Health systems monitor for and evaluate new pandemic threats—a fact that is often underscored by the ad hoc solutions used by scientists to partly work around the limitations of the existing system. Most notably, both the WHO and OIE systems are usually interpreted as focusing on the notification of events (ie, outbreaks) to initiate and inform response, rather than on scientific discoveries. The boundary between the two is blurry in many cases, such as when a retrospective study discovers an outbreak several years after the event itself. The online scientist-run ProMED-mail system, a primary, but not the first, source of information on the COVID-19 outbreak in Wuhan,[1] has also publicised the canine coronavirus and porcine deltacoronavirus discoveries. In contrast, neither discoveries are documented in WHO's DON. Important discoveries about viral ecology similarly rarely qualify as outbreak events. For the goal of spillover prevention, neglecting scientific discoveries from notifications becomes a particularly major problem, given that the schema of outbreaks is rarely applied to surveillance data on viruses that circulate normally—and often with minimal or unknown pathogenicity—in their wildlife reservoirs. There are again no normal channels or obligations for sharing these early discoveries beyond the regular, slow process of peer-reviewed publication. In one case, the Liberian government and PREDICT consortium even chose to release prepublication press releases in 2019 that announced the discovery of a Zaire Ebolavirus genome fragment in a wild bat (*Miniopterus inflatus*), potentially ending a decades-long search for the virus's definitive reservoir and guiding efforts to prevent future spillover.[37]

An additional layer to the complexity of the current approach to notifications is the role of genetic sequence data (GSD). The first sequence of a viral genome is both a key part of detecting an event and often a scientific discovery in its own right; however, substantial scholarship shows that the current system is poorly designed to ensure the rapid and equitable sharing of GSD.[38–40] At present, the IHR does not expressly require the sharing of GSD, and the Meeting of Parties to the Nagoya Protocol is slated to discuss incorporation of digital sequence information into the regime's scope of access and benefit sharing (ABS), as physical samples become increasingly obsolete in the era of high-throughput sequencing and synthetic biology.[41] The movement to incorporate GSD in ABS regimes recognises the importance of equitably sharing the benefits from the use of GSD, including vaccines, diagnostics, and therapeutics, particularly as reliance on physical samples reduces. The implications of inequitable benefits sharing during the COVID-19 pandemic have been striking: as substantial vaccine inequity persisted, so did punitive travel restrictions on some low-income and middle-income countries that shared sequence data necessary for ensuring vaccines remained effective. At the same time, some scholars argue that transactionalising data sharing could delay important discoveries and undermine the global scientific commons.[42]

Towards notification systems for the 21st century

International legal frameworks should reflect the current scientific understanding of disease emergence, and harness the One Health research environment to circumvent outbreaks as early as possible. Changes to existing regulations might lead to incremental progress, but a pandemic treaty offers a new and promising opportunity to reimagine notification systems from the ground up.

Changes to existing frameworks

Some proposals already address the obvious need to incorporate One Health into global governance reform. Under the amendments to the IHR proposed by the USA, if WHO receives a notification involving the competency of the OIE, UN Environment Program, and UN Food and Agriculture Organisation (ie, the Quadripartite partnership for One Health) or other entities, WHO shall immediately notify the relevant organisation, marking the first inclusion of One Health framing of notifications under Article 6 of the IHR. These changes are being considered against a growing backdrop of One Health movement with WHO, including the establishment of the One Health High-Level Panel and the Special Advisory Group on Origins of Novel Pathogens (SAGO). However, all the suggested changes would only improve the process at and after the point of initial notification. It remains unlikely that notifications about animal health will regularly be submitted to WHO even with this change. In parallel to IHR amendments, the OIE codes could also be revised, either to add new notifiable zoonotic pathogens, or to include provisions that resemble something like an all-hazards approach to zoonotic risk. However, WHO would not be sufficiently empowered to engage in this process and protect human health.

As notifications for potential PHEICs are contained under Article 6 of the IHR, it is unsurprising that proposed amendments also include modifying the obligation to share information upon notification of a potential PHEIC to include GSD. Under the text of the USA's proposal, information sharing would voluntarily include the sharing of GSD when possible. Although this proposal might be necessary for global public health, it is not sufficient, as it is voluntary (and unlikely to diverge from existing practices) and any compulsory sharing is unlikely to be extractable from ongoing discussions in other forums about equitable benefits sharing from the use of GSD. Amendments to therefore include provisions for equitable benefits sharing in the IHR could go beyond the legal scope outlined in Article 21 of the Constitution of WHO governing the IHR, namely regulations concerning "sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease".[43] Furthermore, as shown especially with South Africa's notification and sharing of the SARS-CoV-2 omicron (B.1.1.529) BA.1 variant GSD, the 170-year-old incentive structure that the IHR have been built upon—the rapid and comprehensive notification of outbreaks in exchange for a prohibition against unnecessary or discriminatory travel restrictions—has been eroded. A new understanding of the role and limits of travel

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restrictions further impresses the urgency of resolving the current disincentive—and need for new incentives—for rapid and comprehensive notifications.

Opportunities for new international law

A long-standing reactive paradigm is perhaps the most widely understood threat to pandemic prevention efforts, and is reinforced by notification systems that prioritise the most familiar threats to global health security. A pandemic treaty would offer an opportunity to reimagine notification obligations more expansively: a truly all-hazards approach must address information sharing at every stage of disease emergence, particularly outside of the acute phase of an epidemic. If the goal is effective response, information on an outbreak should not be restricted until after the public health impacts become serious. For example, evidence of the (past or present) spillover of any novel virus should be shared urgently, particularly if the pathogen comes from a group known to pose a substantial risk to public health. On the other side of the spillover interface, a One Health approach requires rapid sharing of information about the discovery of new viruses (or variants) of concern in wildlife or domestic animals; evidence of notable shifts in the geographical range or host range of viruses that pose a serious known threat to human health; or other potential discoveries that foreshadow zoonotic emergence or could guide outbreak prevention.

A treaty that adopts this broad and empowered One Health approach would be a much needed global state shift, on the same scale as the post-SARS reimagining of the IHR, and would substantially empower not just the WHO but the entire Quadripartite partnership for One Health in its mission. The treaty can operationalise this approach through three complementary strategies.

First, a pandemic treaty could expand reporting obligations beyond those in IHR Article 6 and OIE Terrestrial Animal Health Code chapter 1.1 to capture the kinds of information discussed above. This task will be constrained not only by member states' willingness to relinquish sovereignty, but also by potential limitations of the treaty itself as a WHO-led instrument. If negotiations were conducted under the forum of the UN General Assembly, the treaty could more directly address multiple international organisations than negotiations conducted solely within WHO's ambit. However, at the present time, the most likely legal basis and forum for the proposed pandemic treaty is under Article 19 of the WHO Constitution—ie, the classic treaty-making provision. As such, the Quadripartite could be actively engaged by member states and WHO's Intergovernmental Negotiating Body in the conceptualisation of reporting obligations, but the scope of reporting obligations will likely be limited in some ways (eg, animal health reporting obligations could ultimately remain limited to OIE). Even still, a more comprehensive notifications regime could inform and benefit new accountability mechanisms such as WHO's proposed Universal Health and Preparedness Review (UPHR), a peer review process of states' preparedness capacities, or other universal periodic review processes that could be incorporated into a treaty. Although member states have pushed back against the use of the UPHR as a mechanism to name and shame underperforming states, transparent assessment and reporting processes can also empower civil society as important actors in international law for holding states accountable.

Second, a pandemic treaty can create and clarify channels for scientific input, capturing real-time information beyond the scope of states' existing and novel reporting obligations to WHO, and connecting scientists more directly to policy-making processes that often underutilise or ignore scientific expertise. Doing so could potentially protect scientists from pressures that currently prevent information sharing, such as gaps in human rights or whistleblower laws. Further clarifying formal and transparent channels that define, enable, and set boundaries around scientists' obligation to the global public, might help mitigate this threat, more easily bypass barriers to state recalcitrance, and add an essential layer to state accountability. These changes would also empower WHO's role under IHR Article 9 and support new post-pandemic institutions. For example, the WHO Hub for Pandemic and Epidemic Intelligence in Berlin, Germany, reflects a growing enthusiasm about open science approaches to outbreak detection and forecasting; similarly, SAGO could greatly accelerate spillover tracing, and might help avoid future public relations disasters like the COVID-19 origins debate. Broader GSD sharing from wildlife disease surveillance might even support the work of the Coalition for Epidemic Preparedness Innovations in pre-emptively designing universal vaccines, which could be deployed earlier from regional stockpiles, thus helping to keep outbreaks from becoming epidemics or pandemics. These key institutions would all benefit from a real-time, One Health approach to the sharing of scientific discoveries. In turn, this solution could form part of a multilateral approach to access and benefit sharing, helping support the global cause of scientific equity without manufacturing a trade-off between equity and open science. Improved channels for sharing scientific information could also help fulfil obligations under the treaty and other legal instruments, which might be harder to track without scientists' express participation in institutional processes.

Finally, a pandemic treaty could improve the functioning of existing instruments through both capacity building and the benefits of the broader One Health approach. As a matter of both efficacy and equity, any expanded obligations to share information and sequencing data, either through IHR reform or in a broader One Health notifications system under the treaty, must be coupled with financing, technology transfer, and capacity building obligations to help ensure equity and self-sufficiency, especially for low-income and middle-income countries.

These One Health investments would both support the work of, and explicitly include the development and maintenance of, a One Health workforce,[44,45] which could support the kinds of scientific discoveries we describe in this report. This workforce would also decrease the adverse effects of funding insecurity on the transparency and speed of scientific publishing. Making the investments would not only benefit outbreak detection, but—alongside the first two strategies we described—also have a synergistic effect that strengthens the IHR. At present, the difficulty of reconstructing reporting obligations in a subjective risk assessment system substantially limits WHO's ability to hold states accountable for failure to share information, particularly when the timeline of key events and discoveries is uncertain.[1] A higher background information baseline will help contextualise obligations after an outbreak becomes an emergency and compel state action earlier, if the global community is aware before an outbreak spirals out of control.

A shift towards broader notification obligations would have a second, more subtle, effect on the health of the international legal ecosystem. Under the IHR, notifications are only compelled in potential emergencies, and therefore inherently disincentivised by the likelihood of travel bans and economic losses. The international norm against travel bans, meant to neutralise this trade-off, has been broken so many times during the COVID-19 pandemic—and vaccine inequity has been so severe, undermining any advantage of early notification resulting in access to countermeasures—that this kind of covenant is now insufficient. The only solution is to make notifications a routine and universal process, to reduce the risk of reactionary travel bans enacted as a panic response without careful consideration of scientific evidence. If a notification system leverages upstream discoveries effectively, and routinely compels outbreak notifications before they become a probable emergency, the incentive to share data becomes the much higher odds that outbreaks will not become epidemics or pandemics in the first place. In doing so, these reforms might help fix the global incentive structures for cooperation that will either make or break a pandemic treaty, and begin rebuilding multilateral trust.

Conclusion

As of June 2022, the Intergovernmental Negotiating Body for the pandemic treaty is convening to discuss the development of drafts of the treaty. In parallel, potential reforms to the IHR are being explored through the Working Group on IHR Amendments, and were discussed at the 75th World Health Assembly in May, 2022. We are at a unique moment of political momentum, when we can address the delays and data governance gaps of the current fragmented collection of instruments and institutions for notifications. International law reform has the potential to create an actualised, coherent One Health approach that might prevent the next outbreak from becoming a pandemic. In doing so, it would also start to build a global health infrastructure that could successfully share information outside of an emergency.

Contributors

The authors contributed equally to the conceptualisation and writing of the manuscript.

Declaration of interests

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