











## Sinopsis

Entre el 20 de septiembre y el 4 de noviembre de 2021, el Centro Petrie-Flom sobre políticas y derecho sanitario, biotecnología y bioética de la Universidad de Harvard, la Universidad Middlesex de Londres, y el Instituto Max Planck de Derecho Público Comparado y Derecho Internacional celebraron un simposio digital titulado "Hacia una legislación internacional sobre pandemias" (en inglés: International Pandemic Lawmaking), bajo los auspicious de Bill of Health y Verfassungsblog. El simposio fue organizado por Alicia Ely Yamín (Centro Petrie-Flom), Joelle Grogan (Universidad Middlesex Londres) y Pedro A. Villarreal (Instituto Max Planck de Derecho Público Comparado y Derecho Internacional) y en él se reunió a expertas y expertos de todas las regiones del mundo en los ámbitos del derecho, la salud pública, la bioética, la ciencia política y la economía. A lo largo de tres comentarios editoriales, así como 26 comentarios visibles en esta recopilación, se examinan distintos puntos torales dentro de los debates relativos a un futuro instrumento jurídico internacional en materia de pandemias, así como cuestiones más amplias relacionadas con la respuesta a crisis sanitarias globales y una justicia sanitaria global.

El simposio incluyó tres webinars (en inglés) sobre temas emergences del simposio, los cuales están disponibles para visualización aquí:

"Beyond the State – Global Health Governance" (22 de septiembre de 2021)

Moderadora: Joelle Grogan; Ponentes: Gian Luca Burci, Sakiko Fukuda-Parr, Aeyal Gross, y Tsung-Ling Lee

"<u>Addressing Scientific Innovation through Pandemic Lawmaking</u>" (19 de octubre de 2021) Moderador: Pedro Villarreal; Ponentes: Ellen 't Hoen, Ciara Staunton, Paul Ogendi y Cassandra Emmons

"Can a 'Pandemic Treaty' Promote Global Health Justice?" (4 de noviembre de 2021)

Moderadora: Alicia Ely Yamín; Ponentes: Sebastián Guidi, Judith Bueno de Mesquita, Luciano Bottini Filho, Manjari Mahajan, Rosemarie Garland-Thomson, Mike Podmore, y Martín Hevia

Expresamos nuestro sincero agradecimiento a Chloe Reichel, así como a los equipos de los blogs "Bill of Health" y "Verfassungsblog".

Cita sugerida: Alicia Ely Yamín, Joelle Grogan y Pedro Villarreal (eds.), Reporte: "Hacia una legislación pandémica sobre internacional: Cuestiones conceptuales y prácticas" (Petrie-Flom Center y Max Planck Institute, noviembre 2021) disponible en <a href="https://petrieflom.law.harvard.edu/resources/article/international-pandemic-lawmaking">https://petrieflom.law.harvard.edu/resources/article/international-pandemic-lawmaking</a>

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# Resumen Ejecutivo

En preparación para la sesión especial de la Asamblea Mundial de la Salud sobre un potencial nuevo instrumento jurídico internacional sobre preparación y respuesta frente a pandemias, este reporte presenta la compilación de contribuciones al simposio internacional, las cuales de forma individual y colectiva examinan temas críticos y puntos neurálgicos en torno a tal ejercicio legislativo. Al analizar la brecha existente entre el derecho nacional e internacional en las respuesta frente a pandemias, el simposio ofreció puntos clave a tomar en consideración en la formulación y redacción de un nuevo instrumento jurídico sobre pandemias.

Un punto esencial, que tuvo eco a lo largo de las contribuciones, ha sido la necesidad de justificar la creación de un nuevo instrumento, o bien reformar los existentes y combinarlos con principios rectores, con atención especial a evitar replicar las inadecuaciones y los fracasos de reformas pasadas del Reglamento Sanitario Internacional.

Un segundo punto clave es reconocer y rechazar la división de los temas de salud en silos. En la experiencia global de la pandemia de COVID-19, lo que ha quedado de manifiesto es que, si bien es una crisis sanitaria, su génesis está probablemente enraizada en la matriz de regulación ambiental; su impacto desproporcionado en ciertas comunidades refleja y atrinchera las divisiones de disparidades socioeconómicas entre el Norte y el Sur globales y a través de comunidades marginadas y excluidas; y, además, la pandemia profundiza las crisis sociales, económicas y políticas. Una visión de la salud como cuestión exclusivamente técnica aísla la toma de decisiones de un escrutinio democrático y una rendición de cuentas, lo cual socava la confianza general en la gobernanza. Asimismo, esta visión no aborda la intersección de los causantes ecológicos, económicos y políticos ni los impactos de COVID-19 que hemos atestiguado y que estarán presentes en futuras pandemias.

Tercero, al reconocer la responsabilidad compartida de prevenir y responder a las pandemias, necesitamos comprender al mismo tiempo que esas cargas no están distribuidas de manera equitativa, y que actualmente son moldeadas por factores más allá del Estado nación. Si bien las respuestas nacionalistas han sido un obstáculo enorme a la respuesta a COVID-19, el simposio subraya que hay múltiples variantes. Por ejemplo, el nacionalismo de cerrar las fronteras para proteger a la población de un país cuando un gobierno carece de acceso a vacunas contra COVID-19 es distinta en cuanto a sustancia y no solo en cuanto a grado que, por ejemplo, el nacionalismo del acaparamiento de las vacunas y los controles a las exportaciones impuestos por la Unión Europea.

Las contribuciones han ilustrado una serie de condiciones necesarias para que la legislación pandémica sea equitativa. Por ejemplo, compartir información epidemiológica es esencial para una respuesta efectiva frente a pandemias: requiere un marco para la gobernanza de los datos, el accesso equitativo, y la institucionalización internacional de la diseminación de la información transparente y la pericia técnica. De manera similar, se necesita involucrar a una amplia representación y participación de múltiples partes interesadas en la formulación y desarrollo de cualquier instrumento que busque prepara y responder a pandemias futuras, incluyendo a especialistas de distintas ramas del conocimiento y a la sociedad civil dentro y a través de países de diferentes niveles de ingreso y recursos económicos. En este y otros puntos, los comentarios subrayan que un énfasis en las "crisis" no es útil; se requieren procesos institucionalizados robustos y marcos jurídicos armonizados en tiempos "normales", pues solo así podrán ser efectivos cuando las sociedades se encuentren sometidas a una presión extrema.

### Comentarios editoriales

# 1. Hacia una legislación internacional sobre pandemias: Cuestiones conceptuales y prácticas

Joelle Grogan en nombre de las editoras y el editor

20 septiembre 2021

Este simposio, "Hacia una legislación internacional sobre pandemias: Cuestiones conceptuales y prácticas", se convocó con dos objetivos principales: aclarar las desigualdades y los desequilibrios expuestos por la respuesta global a la pandemia y abogar por recomendaciones sobre los principios que deberían guiar la elaboración y redacción de un posible instrumento internacional sobre la preparación y la respuesta frente a pandemias.

Un buen principio puede guiar una buena acción, no obstante, para que sea eficaz debe ser algo más que un buen principio; no se necesita solo un buen diseño, sino más contenido. Por ello, estas entradas del simposio publicadas cada día entre lunes y jueves en *Bill of Health* y en el *Verfassungsblog*, junto con los editoriales que las acompañan, se centran no solo en el diseño de dicho instrumento, sino también en su adopción y ejecución.

La pandemia de SARS-CoV-2 ha puesto en evidencia cuáles son las estructuras sanitarias mundiales: expuso las grandes desigualdades e injusticias en el acceso a la atención sanitaria, así como también a la simbiosis entre los derechos humanos, la atención sanitaria, la política, la economía y la ley. Los cierres nacionales, las órdenes de permanecer en el hogar, los cierres de empresas y centros educativos y el consiguiente desempleo masivo, principalmente de trabajadores poco cualificados y eventuales, han afectado de forma desproporcionada y negativa a los grupos vulnerables y marginados, como las mujeres, los niños, las minorías y las comunidades indígenas. Aunque se han pagado sumas sin precedentes por paquetes

de asistencia social, estos fueron ineficaces en impedir <u>el aumento de los índices de pobreza</u> y desigualdad.

Los ejecutivos nacionales, principalmente, brindan una respuesta ante la pandemia y, a menudo, excluyen cualquier coordinación o influencia internacional, lo que representa, en efecto, una nacionalización de la respuesta.

El abismo entre las respuestas por parte del derecho internacional y del derecho nacional al COVID-19 se refleja en la pobreza comparativa de referencias a las normas o estándares internacionales en las acciones y decisiones adoptadas a nivel nacional. Las medidas adoptadas han hecho escasa referencia al Reglamento Sanitario Internacional (2005). El escaso compromiso observable con las obligaciones internacionales en materia de derechos humanos en la toma de decisiones ejecutivas o en los debates nacionales sobre la legitimidad, la proporcionalidad, la temporalidad y la legalidad de las respuestas a la pandemia no hacen más que evidenciar este vacío.

Si bien los llamados a la solidaridad han hecho eco en el contexto mundial del intercambio de información y datos, existen fuertes divisiones en la voluntad de compartir los frutos de ese trabajo en la propiedad intelectual de los diagnósticos y las vacunas. En mayo de 2021, el director general de la Organización Mundial de la Salud destacó con preocupación que solo el 75 % de todas las vacunas se habían aplicado en diez países y, hasta la fecha, menos del 3 % de las personas que viven en estados con bajos ingresos han recibido al menos una dosis, en comparación con casi el 60 % de personas que

viven en estados con altos ingresos. En este contexto, está previsto que en noviembre de 2021 se celebre una sesión especial de la Asamblea Mundial de la Salud para debatir un posible instrumento internacional para estar preparados y brindar una respuesta rápida ante una pandemia.

El simposio pretende no solo informar acerca de los próximos debates internacionales sobre un nuevo instrumento jurídico, sino también ampliar tales debates.

Académicos destacados y voces emergentes de todo el mundo abogarán, entre otras cosas, por lo siguiente: normas reguladoras globales que reconozcan el interés mutuo y prevengan los daños transfronterizos; la integración de perpectivas de género е igualdad interseccional; un marco para la gobernanza de datos; la institucionalización internacional del intercambio de información transparente y de conocimientos técnicos; y, también, los medios por los que los procesos institucionales nacionalizados y aislacionistas para la toma de decisiones en materia de preparación y respuesta ante una pandemia puedan evitarse en favor de un esfuerzo global colectivo y coordinado. El simposio mostrará una serie de perspectivas, desde la adopción entusiasta de un tratado sobre la pandemia hasta el escepticismo que rodea a la geopolítica de tal ejercicio legislativo.

Al organizar este simposio, nos unimos a otras comunidades de académicos y activistas que participan en debates similares en distintos foros regionales y desde diferentes perspectivas disciplinarias y reconocemos el problema del debate aislado. Al publicar nuestros editoriales en inglés, francés y español en blogs con sede en los Estados

Unidos y en Alemania y con webinarios organizados en el Reino Unido que presentan ponentes de todo el mundo, intentamos reconocer este desafío colectivo e invitamos una amplia participación en este debate esencial.

En la apertura de este simposio, ofrecemos algunas reflexiones iniciales: como se ha demostrado, la retórica de la solidaridad y la responsabilidad compartida, a menudo, solo resuena hasta que llega la cuenta. Las apelaciones sobre la importancia fundamental de los derechos humanos deben reconocer las complejidades sociojurídicas subyacentes en su realización en la práctica. Debe reflejarse la capacidad de respuesta en las asimetrías globales. Para la legitimidad normativa y social, la inversión colectiva y la calidad del instrumento jurídico, debe haber un proceso democratizador que incluya una amplia representación y participación de diversos grupos, incluida la sociedad civil, tanto dentro de paises como así también entre países con diferentes niveles de ingresos y recursos.

El instrumento nuevo que brinde una respuesta ante una pandemia debe comprometerse con los límites de las normas constitucionales nacionales u otras normas públicas. Los Estados también deben prestar algo más que palabrería a las obligaciones de los instrumentos internacionales de derechos humanos en la limitación y derogación de derechos. Sin embargo, un primer obstáculo es justificar la necesidad de un instrumento nuevo de esta índole en el que no se reproduzcan las insuficiencias, limitaciones e incapacidades de los instrumentos pasados y existentes.

## 2. La innovación científica y las reformas internacionales sobre pandemias

Pedro Villarreal en nombre de las editoras y el editor

18 octubre 2021

Quizá haya alguna utopía en la que la investigación científica nos pueda proporcionar toda la información precisa sobre la severidad y mortalidad de una nueva enfermedad. Sin duda, algunos (aunque no todos) creen que tal mundo idealizado incluiría modelos matemáticos que pudiesen predecir con exactitud tanto el patrón de una enfermedad como la serie de herramientas para enfrentarlas, tanto médicas como de otros tipos. En esta realidad imaginaria, los datos nos podrían decir exactamente hasta qué punto las medidas restrictivas de salud pública son necesarias en una sociedad determinada para limitar la propagación de un patógeno, y esta información podría ser compartida a lo largo del planeta. Además, en este mundo mítico, no habría distancia entre la investigación y su aplicación, pues los encargados de formular políticas públicas podrían simplemente depender información existente y así tomar la decisión correcta. Existirían mecanismos salvaguarda para evitar la tentación ya sea de alterar los datos científicos, o usarlos para propósitos partidistas. Y, por supuesto, en un mundo ideal, tanto la investigación como los productos de la innovación científica, incluyendo los productos para el diagnóstico, vacunas, terapéuticos V las disponibles para todas las personas, globalmente, sobre la base de la necesidad y no de la capacidad de pago.

Tal mundo no es posible porque la ciencia no funciona así. Sin embargo, el mundo quebrantado en el que nos encontramos subraya el imperativo toral de reflexionar sobre cómo la creación de normas puede apoyar la innovación científica y la equidad en su acceso. El virus SARS-CoV-2 puso de manifiesto los límites de las "recomendaciones científicas objetivas", que evolucionaron continuamente y aún lo hacen, mientras que

modelos matemáticos producidos por el Instituto de Medición y Evaluación Sanitaria (IHME, por sus siglas en inglés) y otros indicadores similares se equivocaron más a menudo de lo que acertaron. En algunos países, recomendaciones científicas fueron claramente manipuladas para servir propósitos partidistas, con consecuencias fatídicas. En muchos otros países, los gobiernos guiados por comités de expertos, como epidemiólogos, infectólogos y virólogos, experimentaron dificultades para dar cuenta del impacto multidimensional tanto de la COVID-19 como de las numerosas medidas restrictivas de salud pública adoptadas para enfrentar la enfermedad. Múltiples estudios han señalado que tanto las políticas laissezfaire que subestimaron la necesidad de otorgar protección, como las medidas restrictivas adoptadas a lo largo de los últimos meses, han impuesto una carga desproporcionada especialmente en personas situación de vulnerabilidad, trabajadores informales hasta personas con discapacidades.

En el nivel global, en vez de que los países fuesen claros y honestos con sus datos, el pintar un panorama positivo de la respuesta nacional a la pandemia prevaleció sobre la información epidemiológica (y de otro tipo) certera. Esta falta de transparencia socavó cualquier intento por contar con un sistema global de vigilancia epidemiológica que aspira a transmitir la información de manera pronta y certera a todos los países, lo cual reveló una muy delgada rendición de cuentas performativa, como Mahajan la califica.

Más aun, las innovaciones científicas conducentes a productos médicos efectivos para diagnóstico, terapéuticos y las vacunas contra la COVID-19 fueron fuertemente financiados con fondos públicos pero han sido

distribuidos conforme a una lógica de mercado que sirve mayormente a los intereses de las compañías farmacéuticas. Aunaue desarrolladas en tiempo récord, como se señala en el comentario editorial que inició este simposio, la gran mayoría de dosis de vacunas ha sido entregada a países ricos, mientras que los países del África Sub-Sahariana ni siguiera han alcanzado las aspiraciones modestas de la Organización Mundial de la Salud (OMS) de una cobertura del 10% para fines de septiembre a través del mecanismo COVAX. Hay una variedad de perspectivas sobre la relación entre innovación científica y regulación de la propiedad intelectual, pero la combinación entre el modelo imperante de patentes y el control exclusivo sobre el conocimiento tecnológico y la capacidad de manufactura son ciertamente inadecuados para enfrentar una pandemia.

Es posible afirmar, como lo predijo Sheila Jasanoff en los albores de la pandemia, que la ciencia "no llegó en un caballo blanco con una solución". Al mismo tiempo, la negación de la ciencia ha derivado en resultados catastróficos en algunos países, como Brasil. Además, la pandemia ha puesto de manifiesto que el mundo en el que vivimos enfrenta una crisis de confianza en las instituciones democráticas de la que el sector salud ya no puede escapar. Hay una "infodemia" galopante en torno a la COVID-19, propagada a través de canales informales, incluyendo de manera no exclusiva a las redes sociales, así como a las plataformas gubernamentales. La desinformación y la información fraudulenta ha maximizado las distorsiones de los hallazgos científicos y ha acelerado movimientos reaccionarios en contra de las respuestas pandémicas a través de países de ingresos alto, medio y bajo.

De manera prospectiva, queda claro que modelos más incluyentes de intercambio de información en el plano internacional pueden y deben ser previstos. Hacerlo requerirá de compromisos robustos de parte de los Estados, mecanismos multilaterales mejorados, así como normas jurídicas que promuevan la separación entre la distribución de los frutos del progreso científico y las intenciones en pugna. Ya sea ceder ante las prioridades del sector privado con fines de lucro, o ante la tentación de usar la investigación como un instrumento geopolítico en vez de un vehículo para la solidaridad, numerosas acciones que hemos atestiguado durante la pandemia de COVID-19 requieren de un mayor escrutinio ahora que el mundo considera un ejercicio normativo pandémico.

Un tema común a lo largo del simposio actual consiste en quién exactamente puede fijar las prioridades en la investigación durante emergencias sanitarias globales. Tal como se ha subrayado en discusiones recientes en la médica Lancet, The conducir investigaciones de vanguardia en el sector biomédico y en otros puede ser demasiado oneroso para países de bajos y medianos ingresos. Asimismo, algunos sugieren que enfocarse en el aspecto de "emergencia" de la pandemia ignora retos sanitarios que son endémicos en muchas partes del mundo, lo cual favorece la priorización del uso de la maquinaria científica y las normas jurídicas hacia problemas que afectan al norte global.

Las contribuciones en el actual simposio abordan estos y otros temas relacionados con la innovación científica y los derechos a los beneficios del progreso científico con diversos matices, mientras que ofrecen una serie de propuestas creativas. El segundo webinar se centrará, particularmente, en los obstáculos incrementar la disponibilidad accesibilidad de las innovaciones científicas durante una pandemia, y cómo un ejercicio de creación normativa durante una pandemia puede ocuparse de la "interfaz cienciapolíticas públicas", como lo discute Gian Luca Burci en su contribución. La pregunta de si el derecho internacional puede proporcionar soluciones a cualquiera de estos retos depende, en última instancia, de la voluntad política prevaleciente de los representantes de gobiernos sentados en la mesa de negociación. Sin embargo, si dichos representantes ignoran la necesidad de revisar las normas sobre el desarrollo, la diseminación y el intercambio de innovaciones científicas en la preparación y respuesta frente a pandemias, entonces sí que estarán perjudicando al mundo entero.

# 3. ¿Es posible promover la justicia sanitaria global mediante un tratado pandémico?

Alicia Ely Yamin en nombre de las editoras y el editor

4 noviembre 2021

En medio de la <u>"catástrofe moral"</u> de COVID-19, vemos un reclamo generalizado en los análisis en este simposio para que cualquier tratado pandémico o modificación del Reglamento Sanitario Internacional (RSI) promueva más justicia en la salud mundial.

Sin embargo, este imperativo ampliamente aceptado de manera universal oculta un amplio abanico de opiniones divergentes sobre la naturaleza y las fuentes de las desigualdades en la salud mundial y, a su vez, sobre lo que habría que hacer si pensáramos más allá de un estrecho pragmatismo del momento.

En este último editorial, intentamos sacar a la luz algunas de los cuestionamientos críticos que subyacen a cualquier futuro tratado pandémico o revisión del RSI.

En un estado democrático de derecho, en el que todxs son, en teoría, miembros iguales de la polis, existe un amplio consenso ético de que las desigualdades en materia de salud son injustas si son el resultado evitable de distribuciones desiguales de factores socialmente controlables. Por supuesto, tal y como la pandemia ha puesto de manifiesto, existen debates intensos sobre qué es evitablemente injusto y qué factores son o deberían ser socialmente controlables, así como sobre la legitimidad normativa de las diferentes formas de control social.

No obstante, esto no explica necesariamente las desigualdades internacionales que surgieron durante o antes de la pandemia. En el simposio, distintxs autorxs abordan de forma implícita y explícita tres fuentes de desigualdades sanitarias globales que se solapan, pero que son distintas.

# Fuentes de las desigualdades sanitarias mundiales

En primer lugar, además de las variaciones nacionales 'naturales' (por ejemplo, topografía, geografía), hemos visto numerosas injusticias nacionales que crean desigualdades entre y dentro de los países. Por ejemplo, lagunas legislativas, reglamentarias y de aplicación que no permiten el acceso a los bienes y servicios relacionados con la salud; y la cultura política o la falta de rendición de cuentas por pérdidas desenfrenadas, corrupción o desprecio gratuito ante el sufrimiento masivo de la población.

En segundo lugar, existen normas, acuerdos institucionales y prácticas internacionales que impulsan las desigualdades sanitarias mundiales. Por ejemplo, el enfoque de <u>Una Salud</u> tiene como objetivo abordar la salud humana, animal y planetaria y da lugar a soluciones trasnacionales. Estas <u>normas, políticas y prácticas que surgen de la interacción transnacional</u>, denominadas <u>'determinantes políticos de la salud'</u> por la Comisión Lancet-Oslo sobre la Gobernanza Mundial de la Salud, incluyen la deuda y el

ajuste estructural; el acceso a los frutos de la investigación y los datos; los acuerdos comerciales; y la gobernanza mundial antidemocrática.

Por último, tanto los factores nacionales como los mundiales que contribuyen a la desigualdad están enmarcados por las que suelen denominarse cadenas de la historia, incluidas las múltiples expresiones del colonialismo material y la colonialidad epistémica.

#### Promover la justicia sanitaria global

Las formas en que lxs comentaristas dentro del simposio y mas allá entienden la naturaleza de las injusticias sanitarias mundiales y las interacciones entre estas fuentes de desigualdad se reflejan de forma ineludible en distintas propuestas sobre cómo promover la justicia mundial a través de una legislación internacional sobre emergencias sanitarias.

Varios aportes sostienen que para llegar a la justicia se necesita ir más allá de la estrecha vigilancia de la enfermedad (el sello del RSI) para mejorar la preparación tanto jurídica como la del sistema sanitario para futuras pandemias con asistencia técnica y financiera interestatal para optimizar los recursos y las capacidades nacionales en los países de menores ingresos.

Algunxs autorxs proponen incluir obligaciones extraterritoriales en un futuro tratado pandémico como forma de reforzar las obligaciones legales generales de asistencia y cooperación internacionales y de colaboración y asistencia internacionales. Algunxs van más allá al afirmar la necesidad de una Convención: Marco sobre la Salud Global (FCGH, por sus siglas en inglés) que movilice esa ayuda internacional no solo para hacer frente a las emergencias sanitarias o la seguridad sanitaria mundial, sino también para fortalecer los sistemas sanitarios universales y equitativos que sustentan el disfrute de los derechos

relacionados con la salud en tiempos "normales".

Otrxs académicxs y activistxs, tanto del simposio como de fuera de él, entienden la naturaleza del imperativo de forma diferente y argumentan que la justicia en la salud pública mundial requiere rehacer el actual sistema de asistencia para el desarrollo y liberar a los países de ingresos bajos y medios de los factores que sustentan la perdurabilidad de la dependencia, incluido a través de a reactivación de las propuestas del derecho al desarrollo y una versión del siglo XXI del Nuevo Orden Económico Internacional (NOEI) aprobado en la Conferencia de Alma-Ata sobre Atención Primaria.

Lxs defensorxs del acceso a los medicamentos, así como otrxs autorxs dentro del simposio y mas allá, han argumentado que un punto de partida para promover la equidad en la salud mundial, así como el goce efectivo de los derechos relacionados con la salud, debe ser la deconstrucción y la eliminación de las barreras estructurales en la arquitectura de la regulación de la propiedad intelectual (por ejemplo, en relación al ADPIC). Una legislación sobre pandemias que no considere la necesidad de crear incentivos diferentes para compartir los conocimientos técnicos sobre vacunas (las 'fórmulas'), transferir tecnología y descentralizar la fabricación de medicamentos y vacunas, reproducirá ineludiblemente la dependencia de la compasión inestable y mezquina del Norte económico, ejemplificada por los fracasos de COVAX.

Además de considerar la perpetuación de la dependencia, los costos de la prevención estructural supondrían una carga desproporcionada para partes del África subsahariana, Asia y América Latina. Por ejemplo, como señalan Maisley y Guidi, frenar la deforestación en la Amazonía para impedir futuras enfermedades zoonóticas —que son responsables de la prevalencia de nuevas enfermedades infecciosas y podría afirmarse de otras enfermedades relacionadas con el

cambio climático— recaería en gran medida en Sudamérica.

Otrxs sostienen que el paradigma de causalidad y prevención codificado en el marco de la seguridad sanitaria mundial es intrínsecamente defectuoso. En este caso, por ejemplo, reducir la demanda de carne no es solo una cuestión de regular la cría de ganado en el Brasil, los países del Mercosur o incluso toda Sudamérica. Por el contrario, reclama cambios estructurales sistémicos de los determinantes políticos de la salud en nuestro sistema alimentario globalizado, financiado y comercializado, que incluye el fortalecimiento de la regulación efectiva en los países ricos donde tienen su sede las empresas transnacionales relevantes, v frenar la especulación en torno a los productos alimentarios cuando ello pueda tener un impacto sustancial.

Por último, varixs autorxs señalan que ejercicio de elaboración cualquier legislación sobre salud global simplemente reforzará la imagen de selectividad colonialista en lo que respecta a qué constituye una crisis si no aborda el tema de enfermedades que arrasa de forma desproporcionada hemisferio sur y que mata a cientos de miles de personas al año, como la malaria y la tuberculosis. Mientras que algunxs académicxs consideran que la reafirmación del liderazgo de los Estados Unidos en un régimen de seguridad sanitaria mundial es un imperativo para la justicia global, otrxs ven la extensión de la influencia estadounidense como una profundización distópica de las sinergias tóxicas entre el control imperialista y los gobiernos nacionales antiliberales en nombre de la "seguridad" sanitaria.

#### Justicia reparadora y derechos humanos

Si nos tomamos en serio la justicia reparadora para las <u>desigualdades basadas en la</u> <u>extracción colonialista</u>, la violencia estructural y la subordinación histórica, las cuestiones relativas a cómo podría contribuir una legislación de salud global se vuelven aún más complejas. Sin embargo, la creciente tendencia a hacer llamamientos retóricos para "descolonizar la salud global" no debería ocultar, como sostiene Seye Abimbola, el hecho de que es imposible que personas con diferentes agendas y posicionamientos utilicen esos términos de la misma forma y se refieran a lo mismo. De hecho, como afirma Gonzalo Basile, una descolonización significativa de la teoría, la política y las prácticas de la salud mundial parece exigir no una visión universalizadora desde arriba, sino enfoques históricamente contextualizados que busquen subvertir los paradigmas epistémicos e institucionales dominantes.

Todos los argumentos normativos están estrechamente enmarcados por lecturas de la historia y, por adoptar la expresión de Nietzsche: «cómo las cosas llegan a ser lo que son». El punto de partida de toda legislación sobre la pandemia debe ser la revisión del RSI de 2005. Meier, Bueno de Mesquita y Sekalala consideran que el RSI garantiza 'incorporación de los derechos humanos' y 'proporciona una base jurídica para alinear el derecho sanitario mundial con la legislación sobre derechos humanos' y 'armoniza la interpretación de los tratados en todos los regímenes jurídicos'. Otros comentaristas, lejos de compartir esa lectura, consideran que el paradigma de la seguridad sanitaria mundial incrustado en el RSI afianza una forma particular neoliberal de gobernanza colonialista en un mundo hiper-globalizado. La protección de los derechos de lxs viajerxs puede ser necesaria para mantener el tráfico y el comercio internacionales, pero aquellxs que mantienen una perspectiva mas crítica sostienen que el propio orden social institucionalizado es fundamentalmente incompatible con el disfrute universal de los derechos humanos en la práctica.

Lejos de que el mantra del enfoque basado en los derechos humanos resuelva estos y otros conflictos, el simposio subraya cómo los derechos, incluido el derecho a la salud, son espacios de profunda disputa sobre las concepciones de la justicia distributiva, así como herramientas de lucha. Una serie de aportes abordan la cuestión sobre si los principios de los derechos humanos pueden integrarse en la gobernanza mundial sin ser cooptados. Algunxs sugieren posibles modos de participación de la sociedad civil en el diseño, así como en la gobernanza, de un instrumento legislativo pandémico.

Como editorxs, no queremos presentar estas cuestiones fundamentales relativas a la elaboración de leyes sobre pandemias y la justicia sanitaria mundial como si estuvieran resueltas. Por el contrario, esperamos que el simposio haya servido para abrir un espacio para mayores debates más allá de las fronteras disciplinarias, ideológicas y geográficas.

### Comentarios

# 1. Governance Needs for Pandemic Preparedness and Response (PPR) How to Ensure the Science-Policy Interface

Gian Luca Burci

September 21, 2021

The COVID-19 pandemic has been characterized by mistrust in science, the manipulation of science for political purposes, the "infodemic" of mis- and disinformation, and a repeated failure to base policy decisions on scientific findings.

The crisis of confidence in scientific analysis is paradoxical and disquieting, particularly in light of increasing international regulation to manage acute or systemic risks and its reliance on science. This so-called "science-policy interface" (SPI) incorporates scientific expertise into global policy-making and regulation in fields as diverse as climate change, biodiversity, and nuclear safety, but it is arguably less developed in global health and in particular for pandemic preparedness and response (PPR).

As international policymakers consider various proposals aimed at preventing another pandemic through better and stronger global rules — whether in the form of a WHO "pandemic treaty," revised International Health Regulations, a UN political declaration, or regulatory framework — the integration of SPI in their design will be of crucial importance for their credibility and effectiveness.

SPI, however, is only one side of the regulatory coin; the other side consists of the normative commitments that must guide national action and international cooperation in implementing measures inspired by scientific consensus.

From this latter perspective, two critical aspects are: 1) <u>compliance mechanisms</u> to assess national progress and challenges,

identify systemic problems, and build mutual confidence among states; and 2) <u>an institutional framework</u> to manage compliance oversight, provide a forum for consensus building and technical support, and turn SPI findings into agreed targets and benchmarks.

Examples of SPI that present interesting features for our purposes are: the Intergovernmental Panel on Climate Change (IPCC), the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), the IAEA Safety Standards, and WHO's standard-setting. All of these examples (excepting WHO's standard-setting) are linked functionally to international treaties.

Some recurring elements in those initiatives should be carefully considered:

1. Institutional framework: IPCC is an interagency program (WMO, UNEP, IUCN) with an independent secretariat, IPBES is a selfstanding intergovernmental program serviced by UNEP, while the other two are part of the regular programs of IAEA and respectively. WHO, The consideration between here is institutional integration versus dedicated framework controlled by participating states. For "One Health" approach, which targets the interface of human and animal health and environmental protection, the parallel competence of multiple organizations may require mechanisms to compile scientific findings and channel them into an intergovernmental process.

- 2. Relations between science and policy: One of the challenges of SPI is to balance the integrity of scientific analysis with political acceptability. In the case of IPCC, summaries for policy-makers are adopted line-by-line by the full intergovernmental panel, in dialogue with the authors, while technical summaries are left untouched. In contrast, WHO guidelines and similar standards are mostly elaborated by the secretariat with the support of experts and technical partners, with governments limited to providing comments. Intergovernmental endorsement scientific findings is seen as more conducive for negotiations, with the notable example of the IPCC, whose periodic assessments have coincided with, deeply influenced, major international legal developments.
- 3. Process: IPCC and IPBES use a structured and public process to select large numbers of authors and reviewers and organize their work, with successive draft reports undergoing intergovernmental review. WHO, in contrast, usually appoint experts from existing internal rosters with relatively limited transparency, and the final outcomes are issued by the secretariat. Considerations of legitimacy and accountability should weigh heavily in considering options for the future.
- 4. Policy-relevant or prescriptive? examples mentioned above are mostly policy-relevant, where SPI leads to findings or recommendations left to the discretion of states. A possible exception are IAEA's safety standards that constitute benchmarks for compliance with the Convention on Nuclear Safety. A different and preferable approach for a future PPR instrument is policy-prescriptive SPI, where the implementation of treaty obligations is assessed against compliance with the scientific conclusions and guidance generated within the SPI process, subject to technical and financial support and capacity-building.

If we consider pandemics along a continuum starting with the identification of pathogens and ending with the deployment of countermeasures, there are several points where SPI is, conceptually, a critical component of future international regulation.

To illustrate this need with an example, we may consider one such time point: the prepandemic identification of pathogens phase and the management and reduction of the risk of spillover of pathogens from animals to humans. In a recent, co-published <u>Lancet</u> comment, I argued that a future pandemic treaty should incorporate "deep prevention" of zoonotic spillover, a legal blind spot between global health law, which focuses on containment of occurring outbreaks, and environmental law, which addresses different risks. This is an area of considerable complexity that is receiving increasing attention given the frequency of outbreaks of zoonotic diseases including (possibly) COVID-19.

Recent research projects, such as <u>Predict</u> and the <u>Global Virome Project</u>, aim at prospectively identifying and characterizing animal viruses of zoonotic potential. Concurrently, WHO, FAO, OIE and UNEP each have been pursuing a One Health agenda, both under their individual mandates, as well as through an intensifying quadripartite cooperation embodied most recently by the establishment in November 2020 of a <u>One Health High-Level Expert Panel</u> (OHHLEP).

Still, the confluence of different disciplines and epistemic communities make coordination and coherence challenging. What is missing from these initiatives, moreover, is the regulatory interface, given the absence of dedicated international legal instruments. Scientific findings are at best policy-relevant, offering empirical bases or guidance for discretionary national or local measures.

The challenge for the negotiators of a future pandemic instrument will be to devise an SPI

framework that will simplify and integrate the inherently complex and intersectoral nature of zoonotic risk management through processes

that are at the same time scientifically cogent and politically conscious so as to inspire and guide intergovernmental processes.

## 2. Whose Global Health Security?

Aeyal Gross

September 22, 2021

The <u>current</u> discussion <u>within the World Health</u> <u>Organization (WHO)</u> of a "<u>pandemic treaty</u>" aims at better solutions to "health emergencies."

But, if this focus on "emergencies" comes at the expense of chronic and underlying issues, including the overall status of health systems, we risk replicating, with this legal instrument, the colonial legacy of international health supposedly left behind with the shift to "global health." This points to the urgent need to rethink what is considered a "crisis" or an "emergency," as part of the effort to "decolonize global health," including global health law (GHL).

The so-called "international health" approach to infectious disease began to take shape in the mid-nineteenth century, as <u>David Fidler shows</u>. The driving motivation behind this approach was to protect Europe and North America from "Asiatic diseases" spreading from Asia and the Middle East. This regime was streamlined and universalized with the establishment of the WHO and its 1951 international sanitary regulations (renamed as International Health Regulations [IHR] in 1969) that replaced the previous treaties and led eventually to the 2005 IHR.

Eventually this regime faltered, as developed countries made significant strides in reducing the threat of infectious disease to their populations and economies following the availability of clean water, sanitation services, and new medical technologies, such as

vaccines. The concern in developed countries shifted to non-communicable diseases.

In the 1980s, however, developed countries once again became concerned with infectious disease, in light of emerging infectious diseases (EID) such as HIV/AIDS, and later SARS and COVID-19, and re-emerging old ones (e.g., tuberculosis and malaria). A new international legal regime suited to these developments was needed, and "global health governance" emerged as the favored strategy. The 2005 IHR revision process embodied the new strategy of global health governance.

This approach is supposed to be "global" and different from obsolete, colonial "international health." It purports to understand the global nature of disease, rather than center on transmission solely in one direction. But, in practice, it seems to replicate much of the state-focused, colonially-tainted international health scheme. As the COVID-19 pandemic has shown, global health governance often favored unilateralism. nationalism. populist self-interest over global solidarity. Vaccine nationalism, vaccine hoarding, and vaccine diplomacy, together with other nationalist and populist reactions to COVID-19, can attest to this.

<u>Sekalala and Harrington</u> point to the speedy nature of security-led responses, which are subject to what they call the "tyranny of the urgent" implying, *inter alia*, the prioritization of rapidly spreading diseases like COVID-19

over endemic conditions like malaria, which impose a much greater burden on the population's health but are less likely to travel. These approaches end up favoring the nations of the global north, reproducing domination patterns typical of European colonialism.

The risks of the "tyranny of the urgent" became apparent during the COVID-19 pandemic when concerns were raised about the potentially disruptive effects of COVID-19 control measures on efforts to combat AIDS, malaria, and tuberculosis. Research shows, for example, that the provision of TB health services (diagnosis, care, and prevention) was severely disrupted by COVID-19 mitigation measures, partly due to restrictions on freedom of movement and the re-allocation of resources, and, more generally, that COVID-19 has caused significant setbacks in the fights against HIV, TB, and malaria. Additionally, funding for non-communicable diseases (NCDs) as a share of foreign aid declined during COVID-19.

Whose security, then, is included in the "Global Health Security" paradigm? The COVID-19 pandemic has illustrated how "Global Health Security" is triggered when new diseases reach, or threaten to reach, the global north. These new threats are viewed as "urgent," unlike endemic diseases, such as TB or malaria, which nevertheless critically threaten the global south.

The current focus on duties surrounding new and emerging pandemics draws attention, resources, and efforts to diseases like COVID-19, which are declared part of the "Public Health Emergency of International Concern" (PHEIC) paradigm under the IHR.

Meanwhile, although diseases like TB, malaria, and AIDS each kill hundreds of thousands in Africa every year, they are not "new," do not travel easily, and are not defined as PHEIC in the IHR, meaning they do not constitute

"extraordinary events" posing a public health risk to *other countries* through their international spread (PHEIC definition, IHR Article 1). NCDs are addressed almost exclusively through non-binding global action plans, strategies, and recommendations. Although some have described the rise of NCDs as a pandemic or crisis, within GHL they are not viewed as "emergencies."

In other words, when infectious diseases endemic to the global south are at stake, there are no specific norms and duties in international law other than general obligations that can be derived from the right to health, though soft law does play a significant role in dealing with diseases that are not part of the PHEIC paradigm.

The focus on "health emergencies" in the IHR seemingly makes GHL a "discipline of crisis," to borrow the term used by Hilary Charlesworth to describe international law in general. COVID-19 has often been described as a crisis and, as Charlesworth shows, the obsession of international law with crises leads us to concentrate on single events or series of events, often missing the larger picture. This promotes a narrow agenda for international law, and creates silence on issues outside the lens of crises. Charlesworth suggests instead that international law should refocus on the structural justice issues underpinning everyday life, a significant lesson for GHL given the concentration on crisis — and especially on events defined as PHEIC under the IHR, such as COVID-19 — in a way that raises the question not only of the focus on "crisis," but also on the biases affecting the decision as to what is a crisis, especially given the paucity of norms within GHL touching on endemic and noncommunicable diseases.

While the content of a prospective pandemic treaty is still to be determined, it is expected to "clarify state obligations to prevent, detect, and respond to pandemic threats and

strengthen WHO powers" to address novel outbreaks with pandemic potential. The suggestions to focus on prevention and adopt a "One Health" approach within a pandemic treaty, and to include principles of equity and human rights are welcome.

However, the focus on novel outbreaks and PHEIC-like situations within a pandemic treaty ignores the need for expanded concern with background issues, NCDs, and endemic diseases, and remains within the restricted and biased "crisis" framework. The proposed pandemic treaty may replicate this bias, unless it includes a complete paradigm shift of what is considered a pandemic of international concern.

# 3. Human Rights and Global Responses to the Pandemic in the Age of Hyper-globalization

Sakiko Fukuda-Parr

September 23, 2021

In 1999, the Human Development Report called for stronger international arrangements to govern people in a globalized world, stating: "the present era of globalization, driven by competitive global markets, is outpacing the governance of markets and the repercussions on people.... An essential aspect of global governance is responsibility to people - to equity, to justice, and to enlarging the choices of all." As the 21st century sped into an of hyper-globalization, new global institutions are urgently needed to protect the public interest. The architecture of global health emergencies is a case in point. Its core agreement, the International Health Regulations (2005) (IHR) remains state centric, catering to national interests, bound to colonial epistemic frameworks, and silent on market power that can trample on human rights. The age of hyper-globalization requires global institutions that enable collective – responses to contain pandemics worldwide, that build on international solidarity and human rights norms, and structures that break free from North-South hierarchies of power and knowledge.

From surveillance to global response

Although the ultimate purpose of the IHR is to protect people from health threats, its objective is not to manage epidemics domestically but to prevent their spread beyond national borders. As Ramakrishnan Gopakumar points out, the IHR is a framework in which the legal obligation "is effectively reduced to inform WHO on the outbreaks. It is an apparatus to maintain the surveillance system to fulfill the above obligation." Yet the risk we face in this era of hyper-globalization with intense flows of people and goods, globally integrated and interdependent economies and lives, and high risks of zoonosis - is another COVID-19, a deadly novel virus that has defied the capacity of the most equipped nations to contain, let alone prevent its outbreak.

The experience has demonstrated the interdependence of countries in containing the pandemic in which 'no one is safe until everyone is safe'; lack of capacity in one country to contain the contagion poses a threat to people elsewhere in the world of open travel. Though the 2005 revision of the IHR introduced the obligation to develop 'core public health capacities', these capacities focus on the prevention of cross-border spread rather than on implementing domestic

containment measures case identification/tracing/quarantine, nonpharmaceutical interventions such as social distancing and hygiene, public communication and building trust, treatment, or mass vaccination. It is therefore not surprising that many countries that had high public health capacities prioritized in the IHR have experienced widespread deaths from COVID-19. Countries such as the US and UK that rated high scores in Joint External Evaluation (JEE) reports for IHR implementation have some of the highest mortality rates from COVID-19, while countries with low JEE scores have had very low rates; overall, the Independent Panel for Pandemic Preparedness and Response concludes JEE scores have shown no predictive value for vulnerability to COVID-19 pandemic deaths. Similar conclusions are drawn for the scores from the State Party Annual Reports, and from the widely referenced Global Health Security Index.

Faced with COVID-19, there has been little disagreement that a global response is needed to contain pandemics. As 25 world leaders stated in their call for a new pandemic treaty: "No single government or multilateral agency can address this threat alone". The past two years have demonstrated the critical role of global cooperation, not only in information sharing, but in the provision of public goods, notably vaccines. The failure of international institutions to mobilize the full potential of global technologies for the 'people's vaccine', the supply shortage to meet global need, and the inequitable distribution is not only a moral failure but a public health policy error that is prolonging the pandemic.

# From international cooperation to human rights obligations

The 2005 revision of the IHR included specific norms for international cooperation, among them Article 44 that refers <u>primarily to public health capacity</u>. But this takes a minimalist approach, limited to collaboration and assistance amongst states 'to the extent

possible' in building public health capacities in the form of activities such as mobilization of financial assistance and technical cooperation. It is premised on the idea that a lack of technical and financial capacity in the Global South is a risk for the Global North. It is a state-centric approach to cooperation rather than one based on the need for global solidarity in an inter-dependent world. This minimalist approach to international cooperation is entirely inadequate to develop global public health responses – such as the development of vaccines, diagnostics, treatments – as global public goods. It is also inconsistent with the conception of state responsibility in international human rights law.

The UN Committee on Economic, Social and Cultural Rights has emphasized the global responsibility of states, noting that 'states have a duty of international cooperation and assistance to ensure universal equitable access vaccines wherever needed' (para to 9). Moreover, states have an extraterritorial obligation, for example that 'corporations domiciled in their territory..... do not violate these rights abroad' (para 8). These global obligations stem from the Right to Health, but particularly from the Right Development (RtD). As asserted in the 1986 Declaration on the Right to Development, 'States have the primary responsibility for the creation of national and international conditions favourable to the realization of the right to development' (Article 3), and goes on to spell out the 'duty to take steps, individually and collectively' for that purpose (Article 4).

This neglected and controversial Declaration lays the groundwork for addressing gaps in global governance as an obstacle to full enjoyment of human rights in the age of globalization. The RtD Declaration takes forward the idea laid out in article 28 of the Universal Declaration of Human Rights that states "Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized". The Declaration introduces

important innovations in departing from the concept of human rights as a protection of individuals against abuse by their own states, and recognizing that actions of states impinge on people outside their borders, and state ability to fulfill human rights are limited by international structural arrangements. It articulates a 'universal entitlement to a human rights-based international order' (100).

In the context of the global governance of health emergencies, the RtD Declaration articulates why states must address the international structural arrangements such as intellectual property agreements that impinge on universal access to vaccines. In contrast to the minimalist scope of international cooperation in the IHR, the RtD requires states to act proactively, stating "States have the duty to co-operate with each other in ensuring development and eliminating obstacles to development... and to promote a new international economic order based on sovereign equality, interdependence, mutual interest and cooperation among all states' (Article 3.3).

# Challenging hierarchies of power and knowledge

The IHR reflects the political economy and geography of global health emergencies that is preoccupied with outbreaks of infectious diseases coming from the Global South that threaten the health of people in the Global North. The assumption was that the Global North would have the technological and financial capacity to respond to an alert. Yet the geography of COVID-19 <a href="has challenged these underlying assumptions">has challenged these underlying assumptions</a> as the outbreak in early 2020 spread rapidly and globally, but with epicenters concentrated in Europe and North America. Ironically, low and middle income countries of Sub-Saharan Africa and

Asia responded more effectively to containing contagion through 2020, using conventional low-tech public health strategies. Prior to the advent of the game changing vaccines and variants, these countries kept mortality rates far below world average levels. Yet there is little interest in the international community in learning from these experiences and public health methods and strategies that were used while global knowledge on pandemic response continues to be dominated by public health theories and practices of the Global North.

Since the 1999 Human Development Report called for governance of markets and its repercussions on people, the pace of globalization accelerated, and the power of private actors in shaping global health structures in their self-interest increased. Despite public exhortations about vaccines as global public goods, governments of the Global North have worked to preserve vaccines as private property. While governments financed much of research and development, pharmaceutical companies intellectual retain the property now control supply and distribution. Governments do little to support transfer of technology to scale up worldwide manufacture, and almost all resist the proposal supported by over 100 countries for a temporary waiver of the TRIPS agreement provisions on intellectual property pandemic related technologies.

Setting out new norms and arrangements for the provision of global public goods for pandemic preparedness and response should be a centrepiece of a new legal instrument that is capable of challenging market power, and builds on human rights principles in synch with the age of hyper-globalization

# 4. Moving Beyond a State-Centric Pandemic Preparedness Paradigm:

#### A Call for Action

Tsung-Ling Lee

September 27, 2021

Despite the World Health Organization's (WHO) recent efforts to broaden participation, the international infectious disease control regime remains state-centric.

As such, the state-centric infectious disease regime violates the fundamental principle of how contagious diseases spread within and across countries — the virus recognizes no national borders, nor does the virus discriminate. The longstanding global health mantra — no country is safe until all countries are safe; no one is safe until everyone is safe — should guide global pandemic preparedness.

Under the WHO's 2005 International Health Regulations (IHR), State Parties are primarily responsible for strengthening their respective public health core capabilities.

Article 54 of the IHR stipulates the annual reporting obligation: member countries are required to report their IHR implementation progress at the annual World Health Assembly (WHA).

Voluntary commitments include Joint External Evaluations (JEE), After Action Review, and Simulation Exercises, which together form the IHR Monitoring and Evaluation Framework, introduced by the WHO to ensure accountability and transparency in 2015.

In particular, the JEE is a voluntary collaborative process which seeks to provide independent and external expert review of member countries' core capacities in 19 technical areas, initiated at the request of the member state. The JEE process plays an essential role in identifying public health strengths, weaknesses, best practices and challenges in countries' IHR core capacities.

Yet, neither the JEE nor the annual IHR reporting processes are open to the relevant stakeholders.

The JEE process remains a technical exercise between the WHO and requested member states. Civil societies, academic institutions, private sectors are rarely involved in the evaluation process. As the JEE assessment often informs national pandemic action plans, accounting for local capacities and inputs from diverse viewpoints can enhance the quality of policymaking.

Likewise, there is no shadow reporting of State Parties' IHR implementation during the WHA.

Rethinking the public health monitoring framework from a good governance perspective is integral to mitigate the scale and magnitude of social and economic disruptions that pandemics can cause. As we have seen, the pandemic's rippling impacts go far beyond public health, penetrating economic and social spheres. Sustained dialogues on pandemic preparedness, including a broad array of actors, can cement shared interests and responsibilities.

The gaps revealed by the COVID-19 pandemic in terms of preparedness and real-world responses should guide institutional arrangement reforms at national and international levels.

The Independent Panel for Pandemic Preparedness and Response points out that the world was unprepared for the COVID-19 pandemic: the existing preparedness measures "failed to account sufficiently for the impact on responses of political leadership,

trust in government institutions and country ability to mount fast and adaptable responses."

This remark offers a starting point for reorienting our thinking towards pandemic preparedness planning. Successful pandemic responses require the public's buy-in. Public inputs in preparedness planning can help increase that buy-in. Evaluating pandemic preparedness should involve collaborative multi-sectoral efforts at various levels of governance.

Experience from the 2014 Ebola outbreak demonstrates that successful infectious outbreak control response necessitates engagement with non-state actors, such as faith-based organizations. Likewise, as the COVID-19 pandemic shows, community health workers are most familiar with local contexts and challenges, and should be part of pandemic preparedness planning. Diversifying viewpoints can engender better quality policymaking and more accurately reflect the needs and demands in local, regional, and global contexts.

The COVID-19 pandemic has shown that to enhance societies' capacities to respond to uncertainties and risks, and to sustain changes in behavioral and social norms, building trust is paramount. Establishing prior channels of cooperation before the eruption of a pandemic can yield social dividends during global health crises. Regular meetings, exchanges, and reporting implementation progress among stakeholders can cement shared responsibilities and interests in a more equitable world by creating multiple public spaces for solidarity.

Thus, the state-centric pandemic preparedness regime is deeply problematic for two reasons.

First, the regime has partly reinforced nationalistic mindsets to the world's detriment. For instance, during the COVID-19 pandemic, countries first competed for <u>essential medical supplies</u>, then for vaccines.

Second, the state-centric regime tends to neglect the health inequalities within countries when evaluating preparedness. Rising disparities in impacts of the pandemic on communities reveals structural injustice pertaining to race, gender and socio-economic status within countries. For instance, child marriage may be on the rise in India, as the pandemic has caused disruption to schooling. In Asia and the Pacific region, young adults will bear higher long-term economic and social costs because of disruption in employment. Elsewhere, minorities, migrant workers, refugees also bear disproportionate impacts from the pandemic.

It is imperative that we engage and empower individuals to ensure governments worldwide are held accountable for strengthening their respective public health core capacities.

Likewise, it is also essential to create institutionalized processes at the national and international levels to enable currently unrepresented and unheard voices to participate in decision-making processes that affect them.

Pandemic preparedness is a global public good, where everyone benefits when the world is better prepared. Until individuals around the world recognize global health vulnerabilities elsewhere as their own, global pandemic response and preparedness is likely to continue as fragmented, nationalistic, and fractured.

## 5. Killing Locally or Killing Globally

### **Inequalities in Framing Cooperation through Pandemics**

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September 28, 2021

Covid-19 made 'pandemic' <u>a buzzword.</u> The world expressed anxiety on the eve of a pandemic declaration from the WHO, a decision monitored as closely as the white smoke for a newly elected pope. Yet, 'pandemic' has no legal value in international law by contrast with a declaration of <u>public health emergency of international concern (PHEIC).</u> It is no accident that the 12<sup>th</sup> Commission of the Institute of International Law issued a report on <u>Epidemics and International Law</u>, which bluntly avoided the term pandemic.

Despite this, for the general public, the role of a PHEIC determination remains unknown. Given the inconsistency in declaring PHEIC (only 6 events between 2007 and 2020), many epidemics of considerable proportion were ignored by the international community. Yet the mismatch in the general public consciousness regarding the legal implications triggered by a WHO declaration of a PHEIC is not as problematic as the way lawyers and public health practitioners reinforce the centrality of a pandemic, a concept that still requires a more solid definition.

As an international instrument potentially moves forward to galvanize 'pandemics' as a legally defined term – and part of global health governance – we must understand the implication that this word has in relation to disparities between developing countries' problems and the interests of their richer counterparts. After all, any pandemic would have originated from one or more national epidemics, but it would require a globally recognized procedure to trigger stronger international obligations. As opposed

to pandemics, though, epidemics have persisted for decades and raged in low- and low-middle income settings from Zika to Ebola, demanding support from international actors.

Firstly, this classification is undesirable by producing an artificial differentiation between diseases of similar urgency and lethality, while pandemics preparedness is at the center of international law. Should tuberculosis, which killed around 1.5 million people in 2019, be less of a priority than COVID-19? Sometimes called merely a global epidemic, tuberculosis bears many similarities with COVID-19. Both airborne diseases very skillful disseminating among vulnerable groups, including those in overcrowded spaces, such as prisoners in Brazil. However, tuberculosis is widespread for decades and has been regarded as endemic to some countries or simply an epidemic, as described by the WHO and the SDGs target to end the disease by 2030.

Thus, the pandemic status is also a political exercise and a way to phrase a crisis according to political interests. As long as some diseases do not reach a pandemic level, they would not elicit the immediate financial help and international cooperation, which has at least been promised (if not delivered) during COVID. By defining the term 'pandemic ' and enshrining it in international law, with a more powerful procedure than currently exists for declarations of PHEICs, international law can cement the higher status of a pandemic in the global health governance, theoretically forcing member States to collaborate with their resources against pandemics. In practice, COVID-19 has shown some de-prioritization effect of a pandemic among donors, which switched priorities about long-term health needs to focus on containing the virus.

As a consequence, pandemic control in international law may have a neo-colonialist impact, such as in intellectual property law, by using the Global South to enforce rules beneficial to major powers. Ultimately, typifying 'pandemic' as a legal category in international law may install a tiered system in which infectious diseases are tolerable, but pandemics are not. This has been, in practice, Similar to tuberculosis, other a reality. communicable diseases may be solely a regional problem for never attaining pandemic recognition. The international response to Ebola in 2013-2016 is an example of the differential treatment to tropical diseases or geographically circumscribed outbreaks. Despite the criticism of this approach, we are still single-minded about pandemics.

This is problematic for countries ravaged by mosquito-borne diseases, such as Dengue or Yellow Fever. Those are countries that should allocate resources for their endemic diseases but possibly would also need to meet international expectations of air-borne disease control and another set of measures to protect the entire world. Their participation would come as the global inequalities made health systems broken and populations vulnerable to diseases spread in the poorest places, such as cholera, Chagas disease, and malaria (which also may be the result of internal economic inequalities).

A PHEIC should be ideally declared to any ongoing health system disruption or calamity in a broader sense (e.g. in the event of a shortage of medicines for non-communicable diseases), but if States devote themselves to pandemics only, there must be attention to inequalities in epidemic control. A pandemic-centered system should be balanced through mutually beneficial arrangements for the development of health systems and access to

vaccines and medicines in non-pandemic infectious control among the poorest States. Therefore, the least that can be offered, for less developed countries battling alone against their own infectious diseases, is to stipulate obligations to address past and geographically-limited epidemics with equal consideration.

proportionate support to Giving nonpandemic infectious diseases would involve a plan of eradication of current epidemics that would not benefit from a pandemic-oriented treaty (as such obligation would arise solely for future-declared pandemics). Any threshold for a global emergency must not be territorialized and geographically excludent to address ongoing health crises less threatening to the Global North. If an outbreak cannot be a global scale hazard (such as cholera in Haiti, even though technically as part of the 7th pandemic cycle of cholera), there should be an efficient international assistance program to monitor and support regional epidemics.

Further, a mutually beneficial agreement should promote health system development in the Global South beyond border control and pathogen surveillance, so poorer governments may be in a position to devote resources to pandemic control (and not become a breeding ground of disease variants after a pandemic declaration as happened today). In return for establishing a system of health security for wealthy nations, developing countries should receive investment in their domestic vaccine production and infrastructure to act upon immunization programs as swift as the leading governments. This would include, in exchange for compliance to pandemic measures, a mechanism to invest in research and develop appropriate interventions to tropical diseases and other epidemics less likely to harm the Global North. Such must consider broader cooperation interrelated policies, including environmental risks. As it happens, more evidence shows that the <u>proliferation of tropical diseases and new</u> <u>pathogens have been accelerated by global</u> <u>warming</u> or even through <u>deforestation</u>, a problem with the digital mark of the Global North.

It is important to note that, from a human rights-based approach perspective, rendering obligations to prevent pandemics superior to epidemics would be potentially in conflict with core obligations of the international right to health (General Comment 14, para. 44.b and c). In order to harmonize the right to health as provided by the International Covenant on Economic and Social Cultural Rights (ICESCR),

States must take steps to combat epidemics, as provided in <u>article 12-c</u>, which does not refer to pandemics.

In sum, communicable diseases prevention cannot just be a richer countries' problem, seen through the eyes of the victims of a pandemic. The essence of epidemic control by virtue of the right to health has never been to differentiate the local to the global. The international community must avoid entrenching in international law a system indifferent to right-to-health core obligations, instead of effectively promoting international cooperation for all communicable diseases.

# 6. Strengthening International Legal Authorities to Advance Global Health Security

Lawrence O. Gostin

September 29, 2021

The COVID-19 pandemic has exposed marked limitations in the International Health Regulations (IHR) and constrained authorities of the World Health Organization (WHO). With a rising imperative to advance pandemic preparedness and response, more than twenty heads of government proposed a new pandemic treaty. This prospective pandemic treaty offers a pathway to develop innovative international legal obligations, strengthening core capacities, good governance, and compliance mechanisms to prepare for novel outbreaks with pandemic potential.

States have provided WHO with expansive constitutional powers to develop global health law. Pursuant to these powers, the World Health Assembly has codified evolving authorities to coordinate international action to prevent, detect, and respond to pandemic threats. In developing global health law under article 21 of the WHO Constitution, the IHR stand as the leading legal agreement to respond to the globalized threat of infectious

diseases. The current IHR, revised comprehensively in 2005 following the SARS-1 epidemic, has near-universal participation from WHO member states, empowering WHO and governments in detecting and responding to public health emergencies of international concern.

However, the COVID-19 pandemic has revealed deep pandemic flaws in preparedness and response, as the IHR have faced limitations in shaping national responses. Just as important, political controversies have weakened WHO governance and institutional capacities. Despite major IHR reforms in 2005, the national and global response to COVID-19 has seen failures to notify WHO promptly of novel outbreaks, delays in declaring a Public Health Emergency of International Concern non-compliance with recommendations on outbreak responses, state health measures disproportionate to public health risks, and a lack of global

solidarity and equitable allocation of health resources, especially SARS-Cov-2 vaccines.

Redressing IHR limitations in shaping national and global responses, new treaty structures will be needed to face future pandemic threats, drawing from article 19 of the WHO Constitution to develop a binding international convention and providing a legal foundation for proposals to develop a new treaty through the World Health Assembly. A Framework Convention strategy could enable states to agree on core principles, which could then be operationalized through subsequent protocols.

As states prepare for World Health Assembly debates in November, they will consider "the benefits of developing a WHO convention, agreement, or other international instrument on pandemic preparedness and response with a view towards the establishment of an intergovernmental process to draft and negotiate such convention, agreement, or other international instrument on pandemic preparedness and response." The O'Neill Institute for National and Global Health Law at Georgetown University (a WHO Collaborating Center) is partnering with the Foundation of the National Institutes of Health to support WHO's Director-General and member states in the pandemic treaty process. We will be hosting a series of expert consultations among key stakeholders in North America, Europe, Africa, and Latin America.

In identifying the specific strategies for preventing, detecting, and responding to future pandemics, this prospective global health convention provides a unique opportunity to articulate key state obligations, with strong compliance and accountability mechanisms for:

One Health. Prioritizing prevention through land management, deforestation, and the effective regulation of wild animal markets and intense human-animal interchange — under a comprehensive "one health" approach across sectors — the new treaty could reduce the

likelihood of naturally-occurring zoonotic spillovers and other novel threats to health security.

Good Governance. It is crucial that the new treaty stresses an evidence-based and rights-based public health response while proscribing and sanctioning iniquitous government actions, including "authoritarian power grabs," continuing monopolies in medical innovations, failure to resource health systems, heightened levels of pandemic-related human rights violations, and an institutional neglect of low-income and marginalized communities.

International Monitoring. In promoting outbreak prevention, detection, and response, strengthened global institutions must overcome obstacles of national sovereignty to monitor disease threats. International institutions like WHO must have authority to verify state reports, publish crucial outbreak data without state confirmation, investigate novel pathogens independently, and institute remedial actions.

Given the massive gaps in the COVID-19 response and the cavernous gaps in access to vaccines and other resources between richer and poorer countries, bold new legal obligations and governance appear not simply justified but a global imperative. It may appear that negotiating norms and compliance measures as varied as One Health through to international monitoring will be arduous — and it will be. Yet, the health crisis the world has faced is unprecedented and so too must be the solutions. If the world cannot come together for bold reforms now, it may never be able to effectively prevent and respond to future pandemic threats. The time is now.

The pandemic treaty can achieve these goals by providing WHO with the legal mandate, sufficient funding, and political legitimacy to become the governing institution necessary to meet this historic moment. COVID-19 is an unprecedented crisis that offers a unique opportunity to reform WHO to effectively

coordinate pandemic preparedness and response across member states, partner with other international organizations, and ensure international assistance and cooperation — establishing governing authorities to overcome the limitations of the COVID-19 response and advance global health security and equity.

WHO Director-General Tedros has boldly stated that "the world cannot afford to wait

until the pandemic is over to start planning for the next one." An innovative pandemic treaty could become a transformative model of global solidarity in the face of common threats, but it will require states to overcome nationalist forces to meet this global moment, with leaders embracing diplomacy across nations to prepare legal authorities for new challenges.

### 7. Limiting Human Rights during Pandemics

### Recommendations for Closing Reporting Gaps and Increasing International Oversight

Cassandra Emmons

September 30, 2021

Sovereign governments have the prerogative to declare states of emergency when sudden, unanticipated events threaten the lives of the nation and its people. In so doing, government decrees sometimes must contradict other international human rights commitments, balancing the individual versus the collective. Established derogation procedures supposed to ensure such restrictions are proportionate, non-discriminatory, and last only as long as necessary (for an overview, see Emmons 2020). COVID-19 has proven that public health emergencies are not equally recognized in either international law or national constitutions; some international treaties permit "limiting" rights in the name of public health rather than requiring derogation, and nationally some governments authorize emergency measures in practice without ever doing so in name. These parallel processes and conceptual gaps create space for governments to restrict individuals' rights with little to no international accountability during pandemics.

In this piece, I recommend a new international instrument on pandemic response be explicit about reporting requirements when governments suspend rights during such

emergencies. These suggestions incorporate advice from the American Association for the International Commission of Jurists' <u>Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights</u> (1985), the International Law Association's <u>Queensland Guidelines for Bodies Monitoring Respect for Human Rights during States of Emergency</u> (1990), case law of the European Court of Human Rights (ECtHR), and learned experience from the COVID-19 pandemic.

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First, public health limitations clauses should be subject to the same procedural safeguards as derogation clauses. The rights to movement, assembly, association, residence, information, and manifesting one's religion are among the limitable rights in most international human rights conventions. However, such limitations subject to clear reporting requirements. The Siracusa Principles place the "burden of justifying a limitation" on the state (para. 12), but do not specify by and to whom or within what expected parameters this should be done, posing a risk that the restrictions could become entrenched or

permanent. To rectify this omission, governments should be required to *notify* international treaty organizations and/or other relevant bodies when any actions taken to combat pandemics impinge upon other recognized individual rights, even when proportionate, necessary, and taken within the scope of a limitations clause.

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Second, I recommend establishing specific reporting timelines when governments limit or derogate rights during pandemic responses. Changes can be made at three points in the process.

A refined procedure should, first, clarify expectations for when the initial notice must be filed. International human rights treaties that permit derogation all require "immediate" notification (European Convention on Human Rights, Article 15(3); American Convention on Human Rights, Article 27(3); International Covenant on Civil and Political Rights, Article 4(3)). Communications technology being as advanced as it is today, governments should be able to notify the requisite international bodies in a timely fashion. In practice, however, there is some latitude. The ECtHR has acknowledged that notification can be mired by the nature of the emergency, either because it develops "gradually" or because of unavoidable administrative disruptions. The Queensland Guidelines recommend initial notice be made within one week (A.4). ECtHR case law provides a loose set of parameters. In Greece vs. UK (1958), the then-European Commission for Human Rights opined that a three-month delay in notification "was longer than can fairly be attributed to inevitable causes and that it was therefore longer than is justifiable." Months-long delays were also criticized in the "Greek case" (1968). In the interim, the ECtHR found twelve days was a sufficient timeframe for notification in *Lawless* v. Ireland (1961). It is, thus, reasonable for a new legal instrument on pandemics to ask governments their to report

derogation/limitation immediately, and no later than two weeks after declaration of an emergency.

Such an instrument should also request an expected date of expiration for the limitations or derogations and mandate updates if the measures are extended. At present, only the ACHR requires this detail in its initial notification (Article 27(3)). Whether and how quickly emergency decrees expire is a national constitutional issue, so where expiration dates are not mandated, a new international instrument could reasonably require periodic updates justifying continued rights restrictions after a predetermined period of time. American states are already in the habit of such notifications: as of 30 June 2021, 11 of the 15 ACHR parties that have formally derogated from the Convention in response to COVID-19 also followed up with information about extensions and changes to the initial order; several issued multiple communiques. The new instrument could justifiably require member states to update human rights treaty organizations on the status of the emergency decrees:

- (a) at the end of the original expiration,
- (b) at the time of extension or expansion, or
- (c) within six months of the decree being active, whichever occurs first.

Finally with respect to timing, the new instrument should set a definitive time frame for formally rescinding the state of exception when the emergency has passed or come under control (Queensland A.4). The Siracusa Principles recommend the government notify the relevant actors the same day that the emergency is terminated (para. 49), as do several of the treaties themselves. This immediacy can be reasonably expected.

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My third and last recommendation is to increase communication between relevant international agencies and expand the roles for

international non-governmental actors. First, intergovernmental bodies should increase information sharing about rights restrictions in common member states. Between January 2020 and the end of June 2021, only 64% of countries that reported derogations as part of their COVID-19 response to regional bodies such as the Council of Europe or Organization of American States also reported those derogations to the United Nations. Automatic recognition of derogation across institutions would close reporting gaps, and facilitate more effective oversight. Additionally, expanding roles for non-governmental actors could improve international assessments of the legitimacy, proportionality, and necessity of rights limitations (Queensland A.3). Nongovernmental human rights monitoring groups

can provide accurate accounts of events on the ground even when a government does not report limitations or derogations. Experts in public health and epidemiology organizations such as the WHO can also assess the scientific necessity and proportionality of a government's pandemic response measures. Combined, these experts can offer policy analyses grounded in science to inform the rest of the international community. A pandemic instrument should thus recognize the changed landscape of the international community and enhance roles for and communication between regional and alobal governmental bodies and especially nongovernmental actors.

### 8. 21st Century Lawmaking in an Interdependent World

Caroline E. Foster

October 4, 2021

A new pandemic instrument should explicitly embrace the three emerging global regulatory standards of due diligence, due regard, and regulatory coherence.

These standards sit at the interface between national and international law to help functionally align the two in ways that will protect and advance shared and competing interests in an interdependent world.

The standards require nations to exercise their regulatory power in certain ways, including demonstrating (i) *due regard* for the international legal rights and interests of others, (ii) *due diligence* in the prevention of harm to other States, and (iii) *regulatory coherence* between governmental measures and their objectives. These international law standards are already implicit in and given effect by the operation of WHO's current International Health Regulations (IHR) of 2005.

As we develop new pandemic instruments, their presence should be made increasingly explicit. Giving a stronger profile to the standards will help generate new political impetus and new legal bases for implementation of world health law, and fit it to 21st century application.

A new pandemic instrument should highlight that nations are required, as a matter of general international law, to exercise due diligence in the prevention of transboundary harm. This will significantly reinforce epidemic outbreak control obligations. Too seldom is it acknowledged that the WHO's IHR presently provide the benchmark for operationalizing this due diligence obligation, as does the Paris Agreement in respect of climate change. Due diligence centrally requires giving effect to core IHR obligations to (a) develop, strengthen, and maintain national surveillance capacity to detect novel outbreaks and public health response capacity, and (b) to notify and

continue to communicate on potential public health emergencies as they unfold, including identifying support needs, information-sharing, and consultation. Due diligence should be recognized as lying at the political and legal heart of a new pandemic instrument and its implementation in national law.

Due regard should also feature foundationally in a new pandemic instrument. This emerging global regulatory standard requires that nations have due regard in their regulatory and administrative actions for the rights and interests of other nations and their populations. Such a standard is increasingly understood as an important underpinning of international law on cooperation.

The standard's application in the multilateral setting is indicated in the World Court judgment on scientific whaling in Whaling in the Antarctic (Australia v Japan: New Zealand intervening). Japan lost this case partly because it had failed as a party to the International Convention for the Regulation of Whaling (ICRW) to give due regard to the recommendations of the International Whaling Commission (IWC) calling assessment of the feasibility of non-lethal scientific research methods.

Due regard requires nations explicitly to analyze the competing considerations involved in their exercise of regulatory power, including effects on those beyond their voting populace, and including by considering recommendations of international organizations. Giving the concept of due regard a central place in a new pandemic instrument will provide a strong political and legal footing to hold nations to account should they consider diverging from the views of international organizations with responsibilities in regard to pandemic prevention and management. Espousal of due regard would complement the exercise of any international emergency powers to adopt binding directives that may be created in light of the COVID-19 pandemic.

Global regulatory standards can be expected to work in synergy with one another. Due regard works especially in tandem with the third global regulatory standard, regulatory coherence. The regulatory coherence standard includes requirements that nations' regulatory measures bear а rational relationship with their objectives, as already seen in administrative law worldwide. Nations must not only commit to specific pandemic preparedness and response aims and targets, they must also design appropriate domestic legal rules and processes to implement them. Regulatory coherence is particularly important, too, in relation to nations' rights to take public health measures "additional" to those recommended by the WHO. Article 43 of the IHR requires that "additional" trade-inhibiting sanitary measures are not unnecessarily restrictive, based on scientific principles and scientific evidence, as well as WHO guidance, and reviewed as relevant. States must notify the WHO within 48 hours and advise the health rationale. Nations may depart from WHO recommendations and take their own, stricter measures, based on national strategies and risk settings, provided they are scientifically supported and characterized by sufficient regulatory coherence. Much of this is paralleled in the 1995 WTO Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement) and regional trade agreements.

The three global regulatory standards discussed here are inherently pluralistic: national sovereignty remains intact, but is conditioned in new ways that actively consider others' interests, consistent with human dignity in governance. The global regulatory standards soften and contextualize the suggested need for nations to "share" sovereignty with the World Health Organization. These global regulatory standards are beginning to appear consistently across diverse regulatory spheres, from trade to oceans law. They provide a vital means of reconciling the substance of nations' competing interests, and will help promote assistance to those in need through capacitybuilding to reduce compliance problems via early detection, monitoring and advance support. They are premised on science-based action at all global legal levels.

These standards should help provide a starting point for conceptualizing the legal foundations of a potential new WHO convention, agreement, or other international instrument on pandemic preparedness and response in the changing 21st century legal landscape when governments meet at the <u>special session of the World Health Assembly</u> in November 2021 to consider the benefits of developing such an instrument.

The implications for the design of appropriate compliance and accountability mechanisms should also be considered. International law's detailed increasingly and pervasive governance of nations' regulatory activity in an interdependent world has implications for the design of mechanisms that can best help achieve the implementation of this law, and of the global regulatory standards by which it is characterized. An emphasis on enabling conduct consistent with nations' obligations, as seen in the Paris Agreement on climate change, is key.

### 9. FRAND Terms for Pandemic-essential Intellectual Property Rights

Kaat van Delm

October 5, 2021

Our international norms are arguably ill adapted to emergencies such as pandemics. In this contribution I discuss a potential remedy one related challenge, namely cooperation amongst competitors for the accelerated development of vaccines. A way to foster cooperation could be the use of fair, reasonable and non-discriminatory ('FRAND') terms to the licensing of pandemic-essential intellectual property rights (IPR). Specifically, states could make participation in public procurement for vaccines by pharmaceutical companies conditional upon accepting FRAND terms for their IPR relevant for vaccine development. I do not suggest changes to the existing rules for allocation of IPR. Rather, I attempt to explore an acceptable limitation of such rights in case of a pandemic.

Transposing the concept of FRAND terms from standardisation to the licensing of pandemicessential IPR has potential because of the concept's flexibility. FRAND terms do not require commitment to specific royalties in advance, therefore leaving room for considering new information such as the monetary value of the IPR concerned or the severity of the health crisis.

I consider the more practical implementation of FRAND terms in a global pandemic context, in line with the European Commission's interpretation stipulated in its Horizontal Guidelines 2011/C 11/01. First, standardisation, the successful vaccine tenderers would provide 'an irrevocable commitment in writing to offer to license their essential IPR [...] on fair, reasonable and nondiscriminatory terms ('FRAND commitment')' to the concerned WHO member states. The 'fair' and 'reasonable' requirements encompass the new information referred to higher. The requirement 'non-discriminatory' relates to the equal treatment of competitors, in line with the FRAND terms' goal to prevent discriminatory royalty fees. However, unlike for standardisation, vaccine developers should not be expected to apply FRAND terms vis-àvis all third parties. Rather, their FRAND commitment should extend to all competitors bound by the same commitment, across the WHO member states. Second, a clear IPR policy should be readily available upon the declaration of a pandemic by the WHO, containing principles fit for the pandemic at stake. Third, a requirement for good faith disclosure of pandemic-essential IPR should be imposed on successful vaccine tenderers. Depending on the developmental stage of the vaccine concerned, the IPR policy could require an ongoing disclosure of relevant IPR, or be limited to disclosure upon committing to the policy.

The proposed regulatory framework consists of three levels. First, the framework falls within the scope of the WTO's TRIPS agreement. Imposing FRAND terms as licensing conditions for a patent concerns a limitation of the rights conferred by said patent. However, as the aim is to foster cooperation regarding research on vaccine development, the framework could benefit from the flexibility included in Art. 30 TRIPS, via a research exception. FRAND terms are inherently well-placed to comply with Art. 30 TRIPS, as reasonableness is a common requirement. The second relevant regulatory level is the national level, concerning member states of both the WTO and WHO. Member states which have transposed the research exception of Art. 30 TRIPS in national law could require vaccine developers to apply FRAND terms to the licensing of pandemic-essential IPR. Such requirement could be imposed via early stage public tenders for vaccines. If not accepted, vaccine developers would be excluded from public procurement, and they would not receive access to potentially relevant IPR from competitors under FRAND terms for research purposes. As finding political consensus for the compulsory introduction of this system is unlikely, WHO member states would participate on a voluntary basis. Also, the prioritisation by member states of vaccines developed on the basis of FRAND terms can only be upheld in so far as it would not jeopardise public health. To ensure a uniform approach by the states, the WHO acts as a third regulatory level. Together with the declaration of a pandemic by the WHO, an IPR policy containing the key aspects of the licensing (FRAND) terms is issued, tailored to a specific pandemic. Such procedure could be formalised by the WHO in an international pandemic treaty or other legal instrument. The new IPR policy would remain

generic, only harmonising what is strictly required to incentivise finding new vaccines against the disease causing a pandemic.

The described framework should remain subject to conditions safeguarding fair competition and compliance with the agreed terms. National courts and competition authorities of WHO member states would perform supervision and enforcement thereof. First, as competition law is not harmonised internationally, supervision will be performed in line with national (or supranational) legislation. Independently of the supervision framework chosen, corporations should in any case 'document all exchanges, and agreements between them and make them available [...] on request' (EU Temporary Antitrust Framework concerning COVID-19) in order to facilitate supervision. Second, it is difficult for courts and competition authorities to assess whether FRAND commitments have been honoured, as 'cost-based methods are not well adapted to this context because of the difficulty in assessing the costs attributable to the development of a particular patent' (Horizontal Guidelines), a statement which can be extended to other IPR. Ex ante disclosure of the most restrictive licensing terms to the supervisory authority may constitute a solution. Upon conclusion of the public tender, vaccine developers communicate their most restrictive licensing terms for pandemicessential IPR, including an estimate of royalties. This could serve as a reference framework for both supervision and enforcement. How the exchange of such information amongst states would take place, is subject to further discussion.

In conclusion, FRAND terms constitute an adaptable framework for vaccine development. Several questions must be addressed to find a good balance: what exactly constitutes 'pandemic-essential IPR'? Up until which phase of vaccine development is it appropriate to share IPR? To what extent is it possible to assess IPR value while vaccine development is still ongoing? Despite these outstanding

questions, FRAND terms for vaccine development could be framed as a flexibility stemming from art. 30 TRIPS, and the drafting of an IPR policy by the WHO is a flexible medium to boost the search for a solution to a

pandemic. It constitutes an interesting baseline for balancing public health concerns and rewarding pharmaceutical R&D.

# 10. International Pandemic Lawmaking: Some Perspectives from Behavioural Economics

Anne van Aaken and Tomer Broude

October 7, 2021

In this brief essay, we wish to highlight some insights from behavioural economics that can contribute to a successful process of international pandemic lawmaking. interest here is not to engage with individual or collective psychological reactions to pandemics or other large-scale risks, or with substantive policy made in their wake. Several such behavioural issues and dimensions have been dealt with elsewhere, not without (ongoing) spirited debate. For example, the utility of simple reminders to get vaccinated as individual 'nudges', contrasting with enforced vaccination is a continuing issue. Indeed, the WHO is addressing such approaches through the Technical Advisory Group on Behavioural Insights and Sciences for Health, in accordance with general UN behavioural science policy. Similarly, elite decision-makers' tendencies towards procrastination and omission bias in the face of high degrees of uncertainty, on both national and international levels have negatively impacted large-scale arguably policies with respect Covid-19. Understanding these and other behavioural dynamics may be crucial in determining the substantive content of a cooperative pandemic regime. Here, however, while building on related frameworks of analysis from the field of behavioral economics, as applied to international law (including nudge theory), our focus is on the process and design of pandemic international law-making.

Our framework of analysis recognizes that international lawmaking processes, including

treaty negotiation, or formulation of 'soft law' (such as unenforceable decisions resolutions of international organizations), all involve strategic interactions between actors – international governmental/nongovernmental organizations and individuals elite decision-makers (negotiators, subjects). These actors are traditionally assumed to be rationally pursuing self-interest and utility-maximization on domestic and international planes, often within gametheoretical frameworks (e.g., here). However, this standard rational choice model is cast in doubt by experimental and empirical research behavioural economics, which demonstrates that the rationality of actors does not necessarily conform to assumptions and expectations. Decision-makers (and at times also corporate actors, such as states) possess forms of bounded rationality (as well as bounded willpower and bounded selfinterest), with various psychological biases and heuristics that may determine their ultimate conduct, not least with respect to public goods. Thus, as a central issue, when faced with risk and uncertainty, actors weigh differently losses and gains of an objectively equal quantum, often more concerned with preventing loss than creating gains ('Prospect Theory'). Accordingly, framing regulatory measures or legal guidelines as either gains or losses can influence their effectiveness (see, e.g., in an environmental context here).

With respect to international pandemic lawmaking, we generally embrace a recent key analysis of the diminished effectiveness of the World Health Organization (WHO) and the Health Regulations International throughout the Covid-19 pandemic, according to which the pandemic raised problems of political cooperation rather than expert coordination, which the to current international legal framework is ill-suited. Indeed, this analysis (at p. 597) also suggests the possibility that "the assumption about rationality is misguided". Combatting pandemics is a collective action problem with well-known incentive deficits. Although arguably it would have been (globally) welfaremaximizing to distribute vaccines equally in all countries in order to prevent variants making vaccines less effective, not even under the veil of ignorance at the beginning of the pandemic of which countries would be hit hardest could states agree on a legal framework to combat the pandemic. This in itself comports with behavioral writing on 'pro-sociality' of states, which is very difficult to separate from national self-interest, and when the stakes are as high as during a pandemic, conduct will tend towards the latter. Having said that, while one possible conclusion is that future international pandemic law needs stricter rules and enforcement mechanisms (which indeed might be the case), we offer some complementary suggestions.

First, international soft law can be surprisingly useful and effective, despite the absence of enforcement mechanisms. This can be attributed to both traditional rational choice explanations and to cognitive effects, such as status quo bias associated with 'default rules', the difficulty to discount soft rules as information, and anchoring effects associated with legal standards (see <a href="here">here</a>). We thus contend that non-binding arrangements with explicit rules should be considered, alongside to or as alternatives to 'hard' law, which might be more politically feasible than, e.g., an effective pandemic convention. The WHO and its members have, for example, used soft law

successfully in the WHO guidelines on packaging and labelling of tobacco products (e.g., when the WTO Appellate Body upheld a dispute settlement Panel's use of non-binding provisions of the Guidelines as evidence of emerging tobacco control practices on plain packaging). In the context of pandemics, such an approach could be perhaps replicated through guidelines on incentives and 'nudges' to vaccination, and the participation of non-vaccinated in public life.

Second, either through hard or soft law, there is a strong case to be made in favor of designing positive 'rewarding' mechanisms to cooperation rather encourage complements) to negative sanctioning against non-compliance. For example, insofar as expedient sharing of information regarding disease outbreaks is a major goal of international pandemic law-making, rewarding source states who provide such timely and accurate information of outbreaks and causes may be more effective than the weak threat of symbolic punishment, especially because it eliminates problems of access and verification. Such conditional rewarding for capable and cooperative states— for example, minimum assurances of international assistance and access to medical supplies and vaccinations, institutionalized initiatives through COVAX— could also address gaps that have clearly emerged during Covid-19 between 'developed' and 'developing' countries.

Third, attention should be paid to the 'ground rules' for negotiation of particular disciplines, such as opt-ins\opt-outs (such as with respect dispute resolution) research demonstrates that states will opt-in significantly less frequently than opting-out; yet this may influence the willingness to commit (reflecting on our previous points). Similarly, positive\negative listing, where relevant – e.g. with respect to mechanisms for the adoption of internationally recognized travel advisories may affect negotiations.

Fourth, again, whether as hard or soft law, the status of international pandemic regulations and decisions should take into account their position as 'floor or ceiling' — either or both. Minimum standards run the risk of being considered as 'anchors' to which no further effort is required (perhaps weakening states' motivation to take 'additional measures' as per Article 43 of the WHO International Health Regulations). Overly stringent regulation (certain types of lockdowns and restrictions on international travel or excessive vaccination conduct) can create negative externalities. For example, national vaccination programs can

come at the expense of global health – thus the application of 'ceiling' regulations may be considered.

There are certainly more fine-grained aspects of behavioural economics that can be very pertinent to both design and content issues of international pandemic law-making. We hope that negotiators will adopt such approaches in overcoming obstacles to agreement and promoting such agreement's effectiveness.

## 11. Taking Data Sharing Seriously

### Public Interest and Solidarity as Principles for an International Pandemic Treaty

Ciara Staunton and Deborah Mascalzoni

October 13, 2021

COVID-19 demonstrated the interconnectedness of the world and that our collective protection and well-being is contingent on our individual response. The importance of solidarity and acting in the public interest became key messages in public health, as too were these principles justified as the basis for data-sharing across borders. Accessing this data was critical and its timely access to this data was essential in research for the much-needed new vaccines.

Solidarity can be understood as the commitment to carry costs to assist others. In the same way that we were told to keep away from loved ones (the cost) to stop the spread of the virus (to assist others), individuals were encouraged to share their data with researchers and in turn researchers were encouraged to share their data with other researchers (the cost) to develop vaccines (to assist) for the global collective benefit (others). The response was remarkable. Data sharing became the default (the cost), vaccines were rapidly developed (to assist), but herein the solidarity pathway stopped. Access was (and

still is) largely driven by national and private interests rather than the global collective benefit.

It is clear from this pandemic that the principles of solidarity and the public interest can help drive the data sharing needed for the quick development of vaccines. Data sharing and data access has thus unsurprisingly been called to be included as part of an international pandemic treaty. However, there is not universal support for data-sharing even in a pandemic, in part due to the issue of benefit. In principle, solidarity and the public interest are principles that should guide a pandemic response, but we have seen with COVID-19 that unless these principles are embedded into legally enforceable conditions that clearly dictate benefit, they are not the basis on which to share data. Data sharing in this pandemic has created an imbalance between the values that underpinned data sharing and the values drove benefit. This is unethical. inequitable, but also creates an environment in which variants can more readily emerge, potentially wasting the global effort to date. A threat such as this pandemic can only be solved as a global response.

Data sharing and global health in a pandemic must be seen as a common that should be regulated and protected. Only a legally enforceable framework can ensure that solidarity is matched with reciprocity that is in the global public interest.

#### So where to begin?

There is a plethora of regulations, legislative frameworks, consortium policies, and other data governance frameworks already in existence that identify key principles to govern data sharing. However, they were not developed for when there is need for immediate and collective global benefit. Furthermore, these rules and policies have largely been driven by high income countries (HICs) that serve a neoliberal agenda where access to healthcare is generally provided. This approach to data sharing fails to consider the reluctance of many researchers unrestricted data sharing that has been criticized as displaying a neo-colonial mentality. There is a double standard in commodification of data: there is the expectation that data will be freely given, but that researchers from HICs who have the technology (technology that is often nonexistent in resource limited settings) to process the data are the ones to receive property rights on the resulting outputs. A first step in developing legally enforceable rules is the decolonization of the conversation on data sharing, that is not based on unrestricted open access to data whereby data producers relinquish all rights to the data. The interests that data sharing currently serves must be recognized and the barriers to equitable data sharing unpacked. It is only then that rules and principles that embed solidarity and the public interest into data sharing practices during a pandemic can emerge.

The next step is identifying the *process* for developing these rules.

The World Health Organisation (WHO) is the international agency with the responsibility for public health. It already convenes Member States each year at the World Health Assembly to decide, amongst other, key policies. It has developed a Global Strategy on Digital Health, recently established the WHO Science Council and has proved itself capable of issuing recommendations on challenging controversial topics such as human genome editing. The WHO therefore already has the systems in place to facilitate the discussion on data sharing rules and could be the appropriate forum in which to develop a framework.

Data sharing rules without accountability mechanisms are pointless, so a third key step in this process is the identification of a body responsible for enforcement of these rules.

Although the WHO may be the moral voice of reason, it may not be the appropriate body. Throughout COVID-19 the WHO's calls for equity and global solidarity in the distribution of vaccines were ignored. We agree with the Independent Panel that the governance of the WHO must be strengthened, but the process will take time and the necessary political will may be lacking. Individual states, however, have the legal power to ensure compliance, but they have proven themselves in COVID-19 to lack the moral conscience to think beyond national interests.

Therefore, there is a need to consider an appropriate body that emerges from this conversation on an agreed set of rules on international data sharing. It will need to be a partnership that is free from pre-existing rules on data sharing for global health, has equal geographical participation that involves individual countries, but also scientific organisations and funders of science. The Access to Covid-19 Accelerator (ACT-A) is a model that could be adopted. It is premised on COVID-19 equitable access to tests, treatments and vaccines, and its data governance framework requires the equitable access to data. What it currently lacks is the power to hold those involved with data sharing to account. Any new partnership must have this power to ensure that the solidarity

pathway is followed from data collection to data sharing, and ultimately access to benefits from data sharing.

## 12. The Pandemic Treaty as a Framework for Global Solidarity: Extraterritorial Human Rights Obligations in Global Health Governance

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October 13, 2021

Rising nationalism has presented obstacles to global solidarity in the COVID-19 pandemic response, undermining the realization of the right to health throughout the world.

These nationalist challenges raise an imperative to understand the evolving role of human rights in global health governance as a foundation to advance extraterritorial human rights obligations under global health law.

This contribution examines these extraterritorial obligations of assistance and cooperation, proposing human rights obligations to support global solidarity through the prospective pandemic treaty.

#### Limitations of Global Solidarity in the COVID-19 Response

Global governance is central to the advancement of human rights in global health.

Although the World Health Organization (WHO) long neglected human rights in global health governance, WHO has increasingly assumed obligations to implement human rights under a United Nations (UN) mandate to mainstream human rights throughout global governance, including in the global response to infectious disease.

WHO secured the incorporation of human rights in the 2005 revision of the <u>International</u> Health Regulations (IHR), with States

recognizing that "implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons." These efforts provided a legal foundation to align global health law with human rights law, harmonizing treaty interpretation across legal regimes.

Drawing from these human rights foundations of infectious disease governance, the UN immediately saw COVID-19 as a human rights crisis. A range of UN institutions released human rights guidance on COVID-19, providing necessary frameworks for pandemic responses across States and international organizations. This human rights guidance embraced not only domestic obligations, but extraterritorial obligations, framing international cooperation in the COVID-19 response, coordination in sharing health resources, and collaboration to reduce economic and social impacts.

However, these extraterritorial human rights obligations have not been implemented in global health governance, with WHO instead pleading for "global solidarity" as a moral responsibility, charitable imperative, and means to collective self-interest. While facing nationalist opposition to WHO guidance and global inequalities in vaccine distribution, WHO has repeatedly implored that "health is a human right," but has stopped short of invoking extraterritorial obligations of international assistance and cooperation.

Through the implementation of human rights, WHO has an opportunity to advance extraterritorial obligations under the right to health as an international legal basis for global solidarity.

### Evolving Extraterritorial Obligations Under Human Rights Law

Extraterritorial human rights obligations speak to State acts or omissions that affect human rights beyond their territory, providing a human rights framework to structure international assistance and cooperation. Positing legal obligations beyond national borders — conceptualizing international assistance not as a voluntary, charitable gesture, but rather as a binding form of reparative and distributive justice to rectify past and ongoing structural harms — States have codified extraterritorial obligations under international human rights law.

These extraterritorial obligations complement States' domestic obligations, recognizing that the enjoyment of human rights in a globalizing world is often determined by actors beyond the territory of a State, including other States, international organizations, and multinational corporations.

As a framework for global governance, extraterritorial obligations include obligations of a global character – to take action jointly through international organizations. The 1948 Universal Declaration of Human Rights first acknowledged a human rights imperative for international cooperation, declaring that "everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized." States codified this obligation under the 1966 International Covenant on Economic, Social, and Cultural Rights, requiring every State "to take steps individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources..."

Through this grounding in international law, extraterritorial obligations provide a binding framework for global health governance to progressively realize the right to health.

Yet, while these health-related extraterritorial obligations have evolved under human rights law, they have found limited application under global health law. States have developed only broad declaratory language on <u>international assistance and cooperation</u> in the World Health Assembly. Leaving States without clear guidance, the IHR obligate States to "undertake to collaborate with each other," but the <u>relationship between these IHR obligations and human rights obligations remains unclear.</u>

As a result, the meaning of collaboration has been left to State interpretation. Without oversight procedures to review State compliance with global health law, WHO has limited authority to clarify these obligations and hold States to account.

#### Codifying Extraterritorial Human Rights Obligations in Global Health Governance through a Pandemic Treaty

The codification of extraterritorial obligations through a pandemic treaty would provide a pathway to strengthen international cooperation to realize the right to health in global health governance.

Even as high-income States in the Global North have challenged the framing of international cooperation as a legal obligation, States in the Global South have emphasized the centrality of such obligations to the universal realization of human rights. These extraterritorial obligations would allow States in the Global South to enter global health negotiations not merely with a plea for charity, but with a right to assistance and cooperation through global health governance.

Mainstreaming extraterritorial obligations in the pandemic treaty would provide international commitments under global health law and facilitate, through proposed institutional oversight mechanisms, accountability for global solidarity.

The right to health can provide the normative basis for negotiations on the pandemic treaty. Clarifying extraterritorial obligations under the right to health, the UN Committee on Economic, Social and Cultural Rights (CESCR) reiterated in 2000 that "it is particularly incumbent on States parties and other actors in a position to assist, to provide 'international assistance cooperation, and especially economic and technical" to support States in realizing the right to health. In the context of the COVID-19 pandemic, the CESCR and UN Special Rapporteur on the right to health have repeatedly recognized that global governance is necessary to realize the right to health, clarifying extraterritorial obligations cooperate with WHO.

These obligations require that States implement the right to health through their engagement with WHO, implementing extraterritorial obligations through global health governance.

The pandemic treaty provides a path to advance human rights in global health law by strengthening extraterritorial obligations. A new pandemic treaty can recognize extraterritorial obligations under the right to health by:

- prioritizing support for low-income States in the Global South;
- cooperating through WHO in coordinating pandemic responses;
- regulating pharmaceutical companies to secure equitable vaccine access; and
- facilitating accountability through complementary monitoring and review mechanisms under WHO and the UN human rights system.

In overcoming nationalist challenges to global health governance, the pandemic treaty can structure global solidarity through extraterritorial obligations, aligning global health law and human rights law in meeting the challenges ahead.

#### 13. Addressing IP Barriers in the Context of a Pandemic Treaty

Paul Ogendi

October 14, 2021

Tackling the question of how to address the needs for sharing scientific research, pooling technology, and know-how in diagnostics, therapeutics, and potential vaccines in future epidemics is fundamental to any pandemic treaty discussion. Moreover, we also need to consider how such a treaty might address potential conflicts with the Trade Related Intellectual Property Rights (TRIPS) agreement.

First of all, market-based solutions do not work in the context of global pandemics as has been demonstrated in the COVID-19 pandemic that is currently ravaging the world. Market-based solutions demand putting too much 'faith' in the private sector, both in terms of capacity (supply chains, etc) and in terms of equity. By relying on the private sector in the context of COVID-19, many countries are struggling to secure adequate personal protective equipment, testing kits, and more importantly life-saving vaccines.

Despite the World Health Organization (WHO) granting emergency use listing of various vaccines, almost all of the vaccination has

happened mainly in developed nations. countries continue Developing to marginalized and even the much acclaimed COVAX facility, which originally targeted vaccinations for at least 20% of the population of low and low-middle income countries by the end of 2021 has run into major challenges (WHO, 8 April 2021). Initially relying on supplies from India, the COVAX programme has failed to meet its targets as a result of the Delta variant overrunning India's 'broken' health care system (Vox, 19 August 2021). Curiously, the Serum Institute of India had prior contractual obligations to ship "1 billion doses for low and middle-income countries" but failed to achieve high vaccination in India (Quartz, 26 April 2021). The result is that, as of August 6 in Africa, 'less than 2% of the continent's population is fully vaccinated' (BBC, 6 August 2021).

As a result of these failures in global institutions, other strategies had to be quickly put in place. For example, the African Union (AU)/African Vaccine Acquisition Trust (AVAT), COVAX, and United States Government collaboration which targets to vaccinate at least 60% of the African population (GAVI, 16 July 2021). Even this proposal may run into serious problems if the virus continues to mutate as it has done in the past.

Due to the failures described above, a radical paradigm shift is needed from a market-based paradigm to one that encourages more scientific collaboration transcending national, regional and global levels. All available knowledge and technologies should be made accessible so that all countries can learn from each other on how best to fight the pandemic. The current paradigm is not only inequitable but inefficient and therefore irrational since it prevents such an approach.

The new paradigm necessitates that the norms underpinning the market-based system should be suspended in the short term to last from the time a pandemic is declared up to the time some sort of normalcy is restored. The IP

system is the main target here and specifically the removal of TRIPS Agreement barriers. This is the reasoning underpinning the request by India and South Africa in October 2021 for a temporary waiver of certain provisions of the TRIPs Agreement for three (3) years at the TRIPs Council (WTO, 25 May 2021). The counter-argument by the EU -the principal bloc opposing any waiver at all-'calls for limiting export restrictions, supporting the expansion of vaccine production, facilitating the use of current compulsory licensing provisions in the **TRIPS** Agreement.' But in the midst of a global pandemic, this tinkering with the current market-based paradigm is unlikely to address any of the inefficiency failures above (WTO, 20 July 2021).

Using the 14 November 2001 Doha Declaration on Public Health and TRIPS Agreement, countries at WTO have already accepted that the TRIPS Agreement "does not and should not prevent members from taking measures to protect public health" (WTO, 20 November 2001). The same sort of language should be given a force of law through an international pandemic treaty so that any future conflict involving the TRIPS Agreement is avoided.

The next problem to be addressed in a pandemic treaty is the prevention of economic and political sanctions that may be imposed by some countries in retaliation in order to protect their IP. A good example is the US Special 301 list, which according to *Medecins Sans Frontieres (MSF)* "violates the integrity and legitimacy of the system of legal rights and flexibilities created by the TRIPS Agreement" (*MSF*, 30 April 2019).

Thus, the international instrument should envisage specific provisions that legally authorize countries to suspend IP rights in the context of global pandemics. An incentive system should therefore be encouraged through the creation of a Pandemic Fund. Countries or individuals that have contributed

significantly to generation of knowledge and technologies should be fairly compensated from this fund by way of an application (KEI Europe, 24 February 2021). However, the release of the knowledge publicly should not be dependent on compensation.

Such a clear pandemic treaty provision may assist countries to resolve the current conundrum whether or not a solution is found at the WTO. In any event, the WTO should not have so much power to determine the fate of populations in the midst of global health pandemics. The WTO is a forum to support a regime of free trade and it is absurd to expect it to work towards protecting global health. The appropriate forum to guide decision-making on IP rights in a pandemic would be the WHO. There is a limit to what trade regulation can achieve in safeguarding public health.

In conclusion, my proposed provisions for any future treaty have three limbs. The first limb

should reaffirm the rights of every country to take action in the context of global pandemics to protect their public health systems and save lives akin to what the Doha Declaration advocates for. It would therefore be prudent to entrench the Doha Declaration in the pandemic treaty to give it a force of law. The second limb should aim at preventing economic and political sanctions especially from developed countries, which have been the net exporters of technological know-how, by creating a Pandemic Fund. This is necessary because political and economic sanctions have a deterrent effect. The third limb should have emphasis on technology strong cooperation/transfer/pooling/sharing so that available knowledge about a particular pandemic is freely accessible to all and cooperation is fostered. This will necessitate the creation of a Pandemic Knowledge Pool and Scientific Fora across the world.

#### 14. The Pandemic Treaty and Intellectual Property Sharing:

#### Making Vaccine Knowledge a Public Good

Ellen 't Hoen

October 15, 2021

The COVID-19 pandemic has laid bare the lack of regulation for the sharing of intellectual property (IP) and technology needed for an effective and equitable response to the crisis.

The Pandemic Treaty (or other legal instrument) scheduled for discussion at the World Health Assembly in the fall of 2021 should focus on establishing the norm that the IP and knowledge needed to develop and produce essential pandemic health technologies become global public goods. It should also ensure predictable and sufficient financing for the development of such public goods.

During the COVID-19 pandemic, the world of science delivered knowledge needed to produce safe and effective vaccines within an unprecedented short time frame, thanks to substantial funding from the U.S., U.K., and German governments in particular.

While scientists globally engaged in collaboration and contributed transparently to the knowledge needed to produce COVID-19 vaccines, there was no mechanism in place to ensure that the resulting manufacturing technologies would be globally accessible.

Once that knowledge was transferred to the private sector, these private pharmaceutical

companies became the holders of the knowledge, related intellectual property, and regulatory dossiers that are needed to bring the products to market. This happened even though COVID-19 vaccine development benefitted from vast amounts of public financing. This financing was not conditioned on the sharing of intellectual property and know-how.

hold The companies that now that manufacturing knowledge refuse to share it outside their trusted circle of contract manufacturers. Together with the hoarding of vaccines by high-income countries, this has led to grave global inequities in access to COVID-19 vaccines. For example, only enough vaccine has been distributed in Africa to give 2% of the population a single dose, as compared to 70% of adults in Europe being fully vaccinated with both doses. Dr. Tedros, head of the World Health Organization (WHO), has called the inequity in access to COVID-19 vaccines, where wealthy nations reach high levels of vaccinations and poor countries close to none, "vaccine apartheid" and has warned that this inequity is undermining the global recovery.

In the early days of the pandemic, the European Union that funded vaccine research committed to ensuring those vaccines would be global public goods. The President of the European Commission (EC), Ursula von der Leyen, publicly stated on 24 April 2020 at a joint press briefing with the WHO to announce a global fundraising initiative, that COVID-19 vaccines would be "our universal, common good." Further, the promotion of COVID-19 vaccines as a global public good was determined a "negotiating directive" and was included in the agreement between the Commission and the EU Member States that established the Commission's mandate to enter into advanced purchase agreements (APAs) with pharmaceutical companies for COVID-19 vaccines on behalf of the member states.

However, the commitment to develop and promote COVID-19 vaccines as global public goods remained aspirational. The final APAs with the companies appear not contain any provisions that would have encouraged the sharing of IP or manufacturing know-how, nor provisions to promote access for low- and middle-income countries to these vaccines in sufficient quantity and at low prices.

Fairly early on in the pandemic, a number of initiatives were taken aimed at voluntary sharing of intellectual property, including know-how and transfer of technology. In May 2020, the WHO established the COVID-19 Technology Access Pool (C-TAP). C-TAP was set up to offer a platform for developers of COVID-19 therapeutics, diagnostics, vaccines, and other health products to share their IP, knowledge, and data with quality-assured manufacturers through public health-driven voluntary, non-exclusive, and transparent licenses. In June 2021 the WHO announced plans for mRNA technology transfer hubs in Africa modelled after the influenza vaccines technology transfer hubs the WHO had launched in 2007. The Medicines Patent Pool expanded its mandate to be able to work on COVID-19 and is working with C-TAP and the mRNA hubs. Multinational pharmaceutical companies have declined collaboration with C-TAP and with the WHO mRNA hubs on COVID-19 vaccines. Recently the German drug BioNTech has announced developer collaboration with WHO on supporting mRNA vaccine manufacturing capacity in Rwanda and Senegal, but these efforts do not include COVID-19 vaccine technology.

So far, none of these initiatives have resulted in licensing of intellectual property and technology transfer agreements that would enable expanded vaccine production.

Separate from the voluntary IP and know-how sharing initiatives, on 2nd October 2020, South Africa and India proposed <u>a waiver of certain obligations under the TRIPS Agreement for the duration of the pandemic</u> at the World Trade

Organization (WTO). The proposal for the COVID pandemic TRIPS waiver was cosponsored by over 60 delegations. The initiative would focus encouraging on technology transfer and building of manufacturing capacity globally by allowing any company with existing or potential manufacturing know-how to produce COVID-19 related technologies without concerns about possible IP infringement and related legal consequences. According to a not-yetpublished status report by the Chair of the **TRIPS** Council of 20 July (JOB/IP/47/Rev.1), despite various formal and informal meetings of the WTO TRIPS Council on the subject, no progress on the TRIPS waiver proposal could be reported.

The COVID-19 pandemic demonstrates that it is difficult to regulate the open sharing of IP/know-how and technology while a global health emergency is unfolding. It would therefore be desirable to have a global legal framework in place that provides for the sharing of such technology and manufacturing know-how, which is triggered by the occurrence of a pandemic. The World Health Assembly special session this November presents an opportunity to start the process to create such a legal framework.

This framework should oblige States Parties to:

 Incentivize the voluntary sharing of IP / know-how (e.g., via buy-outs);

- Compel the mandatory sharing of IP / know-how (e.g., via funding conditionalities);
- Support (including financing) global pandemic IP / know-how sharing, including regulatory data and technology transfer platforms analogous to C-TAP and the MPP;
- Support, including financing, the development and scale-up of production capacity to ensure sufficiency in all regions of the world;
- Support the adequate supply of necessary inputs (e.g., raw materials) for that production;
- Ensure an optimal distribution of pandemic health technologies for public health needs in all regions of the world; and

Support, including financing, the development of new pandemic health technologies, under the condition that the IP/know-how developed with public funding is shared openly.

The practical implementation this of framework will likely require the involvement of a range of actors and agencies beyond the WHO, including the WTO and international mechanisms. Nevertheless. multilateral recognition of the need to ensure the sharing of pandemic health technologies and the IP associated with it could prevent a situation in which the inequitable access to lifesaving technologies is a serious impediment to addressing pandemics.

#### 15. A Shared Responsibility Model

Sharon Bassan

October 19, 2021

"soft law" frameworks, try to bring together relevant stakeholders to the table, help ensure international sharing of medical information, and facilitate equitable distribution of the benefits of research in developing vaccines

and therapeutics. Nevertheless, their application during COVID-19 did not result in effective global governance. Most responses were nationally-focused, lacked global commitment and solidarity, failed to notify the WHO of novel outbreaks, and were non-compliant with its professional recommendations.

Many agree that the solution should be multileveled and structural—a result of the and connection cooperation between participants. The prism of the "shared responsibility model" provides an interesting opportunity to consider potential global health governance models for emergency actions. My refined version of the model is based on Iris Young and Christian Barry's suggested models, and includes two pairs of parameters, engaging and assigning. Engaging parameters locate the involved actors, and explain why they are assigned responsibilities. Assigning parameters address the type of duties each actor bears, and the site where they are expected to take action.

"Engaging parameters", accountability and benefit, redirect attention from those who experience injustice to those who contribute to or enjoy from the status quo. The accountability parameter looks who is accountable for an area where correction and prevention of ongoing structural injustice is required, rather than looking for actors who have contributed to bringing unjust situations about within their actions with the purpose to blame for mal-intent. Such actors could, for example, be those who advance the public's health in national and international contexts. rather than who has contributed to the breakout of COVID-19. The benefit parameter is based on the unjust gain, or relative privilege, contributors may get from the situation. Privileged actors have more power in the structure and are usually those who will have the capacity to change the structure in their favor. It is debatable if anyone gains from a pandemic, but some actors are more privileged than others, have better access to

vaccines, medical equipment or relevant information, thus should play the substantial role.

The engaging parameters enable allocating responsibilities between different kinds of actors, with asymmetric powers, beyond governments. While the engagement of the UN, WHO, or governments is obvious, the accountability parameter may also engage other stakeholders to sit at the table. For example, domestically, representatives from the education systems responsible for student's health, employers' representative responsible for worker's health, or individuals whose accountabilities (to social distance, wear a mask, or get vaccinated) are required overcome the pandemic.

Globally, the benefit parameter should include privileged as well as less privileged countries to include a diverse perspective to needs and the feasibility of solutions in different contexts. The model could be adopted in different contexts, emergency or others, for different goals. Since it is forward-looking, it could focus on healing and minimizing general global health inequalities, beyond the pandemic, or on exacerbated inequalities due to the pandemic. However realistically, emergency goals provide more incentives to collaborate. Issues that are not unique to the pandemic may be addressed in a separate process. Inability of governments to address the pandemic in their border will not only result in greater health impact to their citizens, but will also inevitably affect other countries, capable or not. Since the pandemic does not recognize national borders, the commitment governments should extend beyond national interests. Affluent countries may be assigned duties towards less capable countries, for example to help them negotiate with pharmaceuticals to get vaccines before providing a third boost for their own citizens. Similarly, during pandemic, pharmaceuticals companies who may benefit if their product is used all over the world should be engaged due to their benefit from their product, for which they are accountable and show how they can reduce the spread of COVID-19. In a non-emergency situation they may have a different goal-specific duty, such as to contribute their share to a more extensive international assistance framework, especially where joint action is necessary. NGOs or human rights organizations could represent individuals' interests and strive to increase access to medical resources and minimize health inequalities in specific regions in accordance with specific needs.

"Assigning parameters," connectedness and capacity, address the content and the scope of the expected action, according to positions and authorities actors have within the specific context. The connectedness parameter looks into inter-relations between actors and the commitment they imply towards fellow actors. Connectedness does not mean how each actor is connected to the injustice (the connection to injustice is a preliminary engagement criterion rather than a parameter for assigning responsibilities). Rather, since each actor is differently positioned, not all stakeholders are connected to the goal of alleviating the burden of COVID-19, or reacting to public health crises in the same way. Responsibilities are different in nature and scope, according to the roles, the different values their positions entail, and specific interaction they may have with others. This implies different areas where action should be taken, even by the same actor. For based on their relationship, example, governments may have certain duties to their citizens, for example to allocate and provide vaccines. Governments may have different

sort, albeit parallel, of duties to fellow governments with reduced capacities, for humanitarian example or political commitments. The capacity parameter requires all participants to take independent responsibility within their authority accordance with each actor's level of powers and influence. This effective and practical parameter transfers many responsibilities to stronger, more capable actors who are better institutionally and materially situated in practices they are involved in. The duties assigned through the model are within the authorities those actors normally have, which may hold the potential to improve compliance, despite lack of governance which raises enforcement concerns regarding unmet duties.

Different goals will most likely engage different scope of actors and the bearers of duties may change according to specific contexts, for example, national and international. In a domestic policy-making, the grand majority of the responsibility lies with the state and its institutions. For example, national healthcare providers and public health professionals should be heard at the policy-making level in order to clarify the feasibility of different interventions. In the international sphere, some of the same responsibilities might be shared with international organizations (e.g. WHO) or with other global actors. The international role of states will obviously be different from their role within their sovereignty.

## 16. Strengthening Global and National Governance for Gender Equality in Health Emergencies

Anna Coates

October 20, 2021

An international instrument on pandemic preparedness and response opens a much-

needed space to highlight the centrality of gender inequality considerations in health emergency responses. With an eye to inclusive governance, investment in gender expertise, and strengthening existing normative mechanisms and architecture for gender equality at global and national levels, a new intergovernmental instrument offers an opportunity for future health emergency preparedness and responses to meaningfully contribute to gender equality.

The COVID-19 pandemic has laid bare the urgency of addressing gender inequalities, including violence against women and girls; access to health care, including sexual and reproductive health care; and economic inequality.

The recent resolution on "Strengthening WHO preparedness for and response to health emergencies" covers the range of public health issues involved in pandemic responses and includes general references to "gender responsive" interventions. However, the lack of specificity does not represent the full dimensions of pandemic impacts on gender equality, and therefore may limit meaningful action.

Threats to the provision of, and access to, sexual and reproductive health services (including contraception and safe abortion), and thus to women's sexual and reproductive rights, due to overstretched health services, are indicated in the resolution. The "shadow pandemic" of increased violence against women and girls is referenced.

However, other key gender equality issues remain invisible, such as the increased unpaid care burden on women in the context of school shutdowns and work from home, and how the economic fallout is damaging precious gains in women's economic empowerment. Women already faced a gender pay gap, and over-represented in informal potentially employment, leaving them uncovered within emergency social protection schemes. The gendered digital divide further limits women's ability to take advantage of

innovative economic opportunities generated by containment measures (See: UN Women's related policy brief).

Women are not explicitly mentioned in the well-deserved recognition of frontline health care workers, despite being the majority (for example, according to the Pan American Health Organization (PAHO), women represented 72% of the over 6,000 health workers in the Americas who had died from COVID-19 by January 2021).

Predecessor frameworks have been stronger in their consideration of gender implications. The <u>UN Framework for the Immediate Socioeconomic Response to COVID-19</u> stresses the necessity of a "strong gender equality imperative" across all axes.

However, even so, normative frameworks such as the <u>Beijing Declaration and Platform for Action</u> (BPfA) can be sidelined in the context of emergency responses, despite their relevance. Within the twelve BPfA critical areas, three priorities merit especial note as the backbone of all efforts towards gender equality in the COVID response and hence should be explicitly included within any future related instrument: disaggregated data; institutional mechanisms; and women in power and decision making.

Disaggregated data to assess the extent of the gendered dimensions of the COVID-19 pandemic are limited. The WHO has elsewhere called on Member States to urgently "collect, report and analyze data on confirmed COVID-19 cases and deaths disaggregated by sex and age, at a minimum." However, existing knowledge already opens windows to significant concerns. As the resolution notes, the consequences of COVID-19, "including increasing gender and other inequalities, have further outlined the need for multilateral cooperation." This requires coordination of gender expertise from multiple domains. The UN System's "Minimum" Requirements Checklist for Integrating Gender Equality in the Implementation of the UN Framework for the Socioeconomic Response to Covid-19" outlines practical considerations for gender-sensitive COVID-19 responses and was made possible by strategically pooling existing gender expertise across the UN system. To ensure its full implementation, global governance for pandemic responses should explicitly strengthen existing UN architecture for gender equality, investing in capacity, expertise, and senior leadership across all entities, including within the WHO as part of its leadership role in "global coordination and cooperation."

Similarly, any instrument on pandemic preparedness and response needs to fully engage with existing normative mechanisms for gender equality. At global level, the Commission on the Status of Women (CSW) facilitates a unified voice to state and amplify shared priorities and commitments amongst national machineries for the advancement of women / gender equality. National gender equality mechanisms require strengthening for adequate representation and coordination of gender concerns in national pandemic response governance. As noted elsewhere more generally, attention to Committee on the Elimination of Discrimination against Women (CEDAW) country recommendations would help identify strategic priorities to be addressed in specific settings in the context of health emergencies.

The needs and interests of women and girls half the population affected by pandemics need their own voices in the task forces, working groups, and political and scientific committees that form the backbone of response governance at global and national Equal participation, leadership, experiences, perspectives, and world views of women in all their diversity should be made explicit in any instrument for inclusive and effective COVID-19 responses that reflect the uneven consequences of gender inequalities among women according to ethnicity, migratory status, (dis)ability, sexuality, and gender identity, and other social axes. The WHO resolution outlines civil society's role in supporting implementation of "multisectoral national action plans." Also being explicit about their accountability role and the representation of diverse women's voices would pivot this role to one geared towards motivating transformative action.

COVID-19 responses risk exacerbating gender inequalities. But this juncture also presents an opportunity to advance the rights of women, girls, and those of diverse gender identities. An international instrument on pandemic preparedness and response should seize this foothold and advance gender equality through inclusive global and national governance.

### 17. The Right to Participation in Global Health Governance

#### **Lessons Learned**

Sara (Meg) Davis and Mike Podmore

October 21, 2021

What should the role of those most affected by pandemics be in future pandemic governance and co-ordination mechanisms?

Drawing on human rights standards and principles, and on existing structures in the HIV, TB and malaria sectors, we argue that the human right to participation should extend to

permanent seats and votes for civil society and affected communities on governance boards.<sup>1</sup> Our argument is informed by an <u>analysis by STOPAIDS</u>, Aidsfonds, CSSN and Frontline AIDS, by consultations led by STOPAIDS, and by the examples of the Global Fund to Fight AIDS, TB and Malaria ("the Global Fund"), Unitaid, and the Access to Covid Technologies-Accelerator (ACT-A).

The right to participation is now widely accepted in development cooperation. Under international human rights law, this right is grounded in the rights to information, freedom expression, peaceful assembly association, and freedom of political and other opinion established in the International Covenant on Civil and Political Rights. The right to participation is articulated in other human rights treaties that are binding on states, including the Convention on the Elimination of Discrimination Against Women, Convention on the Rights of Persons with Disabilities, and the International Convention on the Rights of All Migrant Workers and Members of their Families.

The content of this right has been elaborated by human rights treaty bodies and special procedures, as well as in other statements of soft law: the <u>Declaration on the Right to</u> Development, the Declaration on the Rights of Indigenous Peoples, and the Guideline for States on the Effective Implementation of the Right to Participate in Public Affairs. UN member states further committed to upholding participation rights through the Sustainable Development Cooperation Framework. Global community networks successfully pushed UNAIDS to institutionalize the Greater Involvement of People Living with HIV/AIDS (GIPA) principle. Member states endorsed the GIPA principle again in the 2021 UN Political Declaration on HIV and AIDS.

In practice, interpretations of the right to participation vary. Certainly, it includes a right to be consulted throughout decision-making processes. Consultation is widely recognized in development cooperation, with good examples in health. For example, the Global Commission on HIV and the Law held regional dialogues with lawmakers, policymakers and communities to interrogate the relationship between law, human rights and HIV. This resulted in new analyses, tools, and national reforms, work that continues today.

Considering the unprecedented suffering caused by COVID-19, any future pandemic lawmaking should be informed by public consultations that prioritize hearing the experiences of people most affected by the crisis, and that facilitate their identifying the redress and reforms they want. Such a process will be critical to rebuilding trust in public institutions.

However, consultation, whether to inform the drafting of a legal instrument, or in the establishment and governance of any mechanism that instrument may establish, is likely to have a minimal effect unless it is backed up with permanent governance seats and votes for these communities.

The failures of the ACT-A are a case in point. The ACT-A's poorly-designed structure favors the priorities of the Global North, lacks meaningful representation from the Global South, and marginalizes civil society and communities affected by Covid-19. In our experience, it took a fight to get civil society and communities representation into all the pillars of the ACT-A. Once included, they joined ACT-A working groups, but had little opportunity to input meaningfully, with real decision-making happening behind closed doors among powerful agencies. In a context of global vaccine inequity, civil society inclusion in the ACT-A has given legitimacy to

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<sup>&</sup>lt;sup>1</sup> We use both "communities", to describe those most affected by a disease, and "civil society", which may include organizations led by those not directly affected.

decisions, even though their input has either not been sought or been ignored.

The Global Fund has also struggled to fulfill the right to participation. Many implementing states that receive Global Fund financing still fail to include key populations (sex workers, LGBTIQ+ people, people who use drugs) in national governance and programming. One 2016 community-led survey of African key populations shared allegations of tokenistic consultation, and of threats of retaliation by powerful national actors.

However, there is a strong organizational commitment to meaningful participation at both Unitaid and the Global Fund Secretariats; permanent seats and votes were established early on for community and civil society on their governance boards. Similarly, UNAIDS was the first UN programme with formal civil society representation on its governing body. While many challenges still remain, these structures have made community input more difficult to ignore.

This is in part through design. Representatives on these boards benefit from a steady flow of input from national and global networks of key transnational populations, networks women's groups, trade unions, faith-based organizations, and many others in every region. The structure of voting on the Global Fund board, and the requirement to include civil society and community on powerful standing committees, creates multiple openings for internal debate that leverage underlying input. Important attention has also been paid to governance culture, explicitly recognizing power imbalances and building relationships of trust among diverse board members.

Each civil society and community delegation tries to ensure gender balance, have representation from all geographic regions, as well as to ensure technical expertise on each of the three diseases and cross-cutting topics such as intellectual property, medicine, health systems, epidemiology, programming, etc.

Delegations that fail to be inclusive face criticism by their constituencies, or by peers on the board.

This representation and consultation structure (supported by funding from the Secretariats) civil society and community delegations on the board to escalate concerns from national and community levels and to push the board and Secretariat for solutions, a "boomerang effect" in which advocates who are blocked locally can directly access global mechanisms. As a result of the work of these delegations in partnership with constituencies: millions more in funding has gone to address human rights and gender inequality, human rights and gender equality has been institutionalized in the Fund's strategy and technical guidance, and key populations representation is now an eligibility requirement for the over 100 national CCMs that manage millions in HIV, TB and malaria financing.

We argue that the right to participation as institutionalized in the HIV, TB and malaria responses should not be limited to these sectors but apply equally to all. The development of any future treaty, and design and operation of any resulting new global health mechanism, should include such formalized roles.

It is critical that these representatives are selected through a legitimate, open and transparent process that is led by civil society themselves, as is normally done for the Global Fund and Unitaid, and as was also done in the case of the ACT-A Civil Society and Representatives Platform. Once the mechanism is established, financial support from the host institution should enable civil society and community delegations to convene and consult with those they represent; fulfilling the right to participation should not leave rights-holders with a financial deficit.

The increasing reduction in civic space, including sweeping attacks on civil society,

coupled with the criminalization of and widespread discrimination against particular groups in many countries, means that many consultation processes fail to capture all voices, and that rich local experience fails to shape global health decision-making. It is more

important than ever to ensure that the most marginalised have a voice and a vote in their own future.

# 18. The Import of the UNCRPD and Disability Justice for Pandemic Preparedness and Response

Joel Michael Reynolds and Rosemarie Garland-Thomson

October 25, 2021

During the COVID-19 crisis, many nation-states did not consult or substantively take into consideration treaties protecting the rights of people with disabilities when developing their pandemic responses.

For example, the United Nations' 2008 Convention on the Rights of Persons with Disabilities (UNCRPD) is an international human rights treaty intended to protect the rights and dignity of all persons with disabilities. It articulates principles of non-discrimination (see especially Articles 2, 3, and 5) and broader obligations upon specific parties, such as states parties, which are obligated to protect the rights and freedoms of people with disabilities (see Article 4, et al.).

The failures to uphold these principles and obligations during the COVID-19 pandemic were met with a swift response. The Office of the United Nations High Commissioner for Human Rights (OHCHR) produced guidelines on COVID-19 and the rights of persons with disabilities in April of 2020, as well as a policy brief in May of that year.

This commentary outlines three of the more important considerations for international pandemic lawmaking — both for specific instruments and wider deliberation — with respect to people with disabilities in general and the United Nations' 2008 Convention on

the Rights of Persons with Disabilities (UNCRPD) in particular.

### Three Core Takeaways from the UNCRPD for Pandemic Preparedness and Response

1. Triage or other sorts of critical care policies that specify differential treatment on the basis of disability alone are in conflict with the UNCRPD.

Article 4.1.E states that states parties should "take all appropriate measures to eliminate discrimination on the basis of disability by any person, organization or private enterprise" (see also 5.2 and 11).

Policies could be developed that allow differential treatment options depending upon specific medical information. For example, if there is one ventilator left and two patients are indicated for ventilator use, specific information about the likelihood of response to intubation could, arguably, be used to determine which patient gets it.

Contrast this particularized approach to one that instead stipulates "those with pre-existing respiratory impairments should be deprioritized during crisis standards of care." On our interpretation of the UNCRPD, the latter is unjust and discriminatory while the former is, at least arguably, just.

Further, judgments based upon long-term predictions are not appropriate. This is in line with the OHCHR's guidance on the subject matter, which advises against "triage guidelines for allocation of scarce resources with exclusion criteria based on certain types of impairment, having high support needs for daily living, 'frailty', chances of 'therapeutic success', as well assumptions on 'life-years' left should they survive.

Solomon et al. expand on this, arguing that "the ability to predict long-term survival is poor and therefore susceptible to bias. Furthermore, many disadvantaged populations have reduced life expectancy, and triage protocols should not exacerbate health inequities." Given the evidence suggesting that quality-of-life metrics are biased negatively impact equity of care for disabled people, they agree that "scoring systems using quality-adjusted or disability-adjusted lifeyears should not be used." They do suggest, however, that "near-term survivability...can be assessed independently from disability," where "near-term" picks out 12 months or less from discharge.

2. In the spirit of <u>Article 4.1.H</u>, official information concerning the pandemic must be made as accessible as possible.

This means including closed captioning as well as sign-language interpreters for all pandemic-related communications; it also means ensuring the availability of high-speed internet to all people as well as accessibly designed web interfaces (usable for those with screen readers, etc.) There are many <u>resources available</u> to help various bodies increase the accessibility of their communication strategies.

3. People with disabilities should be included in the development and review of pandemic preparedness and response at all levels and with respect to all relevant institutions.

Article 29.B specifies that state parties shall "promote actively an environment in which

persons with disabilities can effectively and fully participate in the conduct of public affairs, without discrimination and on an equal basis with others, and encourage their participation in public affairs." This includes any potential negotiations of new legal instruments relating to pandemics.

For more detailed analyses and suggestions, including those that take into account broader economic concerns, we recommend the following pieces:

- United Nations, "Policy Brief: A
   <u>Disability-Inclusive Response to COVID-</u>
   19"
- United Nations OHCHR, "<u>Covid-19 and</u> the Rights of Persons with Disabilities: Guidance"
- Banks et al., "<u>Disability-Inclusive</u> <u>Responses to COVID-19: Lessons from</u> <u>Research on Social Protection in Low-and Middle-Income Countries</u>"
- Guidry-Grimes et al., "<u>Disability Rights</u>
   as a <u>Necessary Framework for Crisis</u>
   <u>Standards of Care and the Future of</u>
   Health Care"
- Solomon et al., "<u>Covid-19 Crisis</u>
   <u>Triage—Optimizing Health Outcomes</u>
   and Disability Rights"

#### From Civil Rights to Human Rights

It is worth noting that while the United States of America signed the UNCRPD in July 2009 during the presidency of Barack Obama, it has not been ratified by the United States Senate. The Leadership Conference on Civil and Human Rights notes, "After four years [2016-2020] of an administration that has attacked disability rights through its policies and appointees...the United States must make its position on disability rights clear. Ratifying CRPD represents an opportunity to take bipartisan action and unite with the rest of the world in advancing the civil and human rights of with disabilities people everywhere...Disability rights are civil and human rights. Now, more than a decade after the United States signed the treaty, it's time to finally make a global commitment to protecting disability rights by ratifying it."

While civil rights/anti-discrimination laws like the <u>Americans with Disabilities Act</u> in the U.S. or the <u>Disability Discrimination Act</u> in the U.K. are certainly steps in the right direction, they are <u>insufficient</u> to forward disability justice and to enforce human rights that are inviolable

regardless of ability status. National responses are limited. We encourage the development, implementation, and enforcement of international laws designed to uphold disability rights and realize disability justice across borders. Whether during times of crisis or times of calm, defending disability rights is essential to all human rights efforts at local, national, and international levels.

#### 19. Towards Member-driven International Pandemic Lawmaking

Ching-Fu Lin and Chuan-Feng Wu

October 26, 2021

The COVID-19 pandemic has blatantly exposed the flaws of the World Health Organization (WHO) and its International Health Regulations (IHR) addressing cross-border communicable diseases. Commentators have examined the IHR's decades of struggle in fulfilling its objectives to control cross-border pandemics such as COVID-19, pointing out problems over the level of obligation, precision of language, delegation of power, settlement of dispute, and lack of enforcement power, among others. What has been overlooked, however, is the crucial question of whether the institutional design of the IHR enables the WHO and its Member States to deliver good global pandemic governance.

We argue that the IHR is ill-designed: its rules and mechanisms are disproportionately tied to the Director General's (DG) exercise of power, rendering insufficient member access to and participation in core decision-making and greater tendency of regulatory capture. For example, the IHR <u>failed</u> to facilitate the timely declaration of a Public Health Emergency of International Concern (PHEIC) due to the DG's and the Emergency Committee's misinterpretation and misapplication of rules allegedly driven by political considerations. On 23 January 2020, even when COVID-19 cases had already been found outside of China, thereby indicating the risk of cross-border

transmission (IHR Article 12(4)(e)), the second meeting of the Emergency Committee <u>decided</u> to <u>confine</u> the definition of "international spread" to "having <u>actual local spread</u> of COVID-19 in a country beyond China," instead of "having the <u>potential</u> for, or a <u>risk</u> of, crossborder transmission," and refused to declare a PHEIC. The WHO is also criticized for abusing its bureaucratic influences to <u>further the agendas of individual Member States</u> like China, letting <u>politics override science</u>.

Clearly, an institutional design overhaul is sorely needed for the future of international pandemic lawmaking. To make headway on this goal, we argue that the new treaty should embrace a member-driven rather than a DG-oriented governance model, to be supported by mechanisms that ensure civil society inclusiveness and public reason. A framework convention could be a promising first step in this direction.

The WHO Constitution empowers the WHO to adopt two legal instruments to achieve global health: Article 21 "Regulations" and Article 19 "Conventions" — both are technically "treaties" but demonstrate different strengths and weaknesses. A framework convention can better address pandemic control challenges because its institutional design generally allows for regular review, deliberation on

emerging issues, and progressive/adaptive lawmaking, thereby creating more room for Member State access, deliberation, and decision-making. This is particularly desirable in the rapidly changing and unpredictable context of pandemic control.

Compared to a full-fledged convention, which includes comprehensive and deep commitments and incurs cumbersome negotiations, a framework convention draws political momentum more easily, as it focuses on core principles, priorities, and targets for pandemic control, presenting a model that puts aside political disagreement over specifics. The framework convention constructs a forum for Member States (usually a Conference of the Parties) to deliberate, because basic principles, rights, obligations set out in the framework convention need further clarification and elaboration through guidelines or protocols negotiated and adopted by State Parties. This normative structure ensures a member-driven process with direct engagement, consensus building, and regular exchange of views and information. In the issue area of global pandemic control, it is imperative to enable full stakeholder participation and facilitate a continuing process of treaty evolution that encourages adaptive and innovative solutions in response to dynamic and complex risks patterns and scenarios.

While the WHO is formed by its Member States, it does not automatically entail member-driven governance. Rather, it has been dominated by its bureaucratic bodies and technocratic traditions. While the WHO has previously deferred to national governments' agendas when formulating pandemic control actions, these practices by no means demonstrate member-driven international pandemic lawmaking because such deference is usually paid to the sovereignty of one individual Member State rather than based on the collective will or consensus. By contrast, a framework convention systematically solicits a wider scope of interests, views, expertise, and

agendas from State Parties (and beyond), especially when they convene to negotiate upon and shape the forms and substances of detail-oriented, readily operational implementation guidelines and protocols.

A member-driven rather than DG-oriented governance model embedded framework convention can also alleviate legitimacy and accountability deficits and enhances transparency. For example, the emergency power plays an important role in global pandemic control, and the WHO's technical expertise is usually a source of legitimacy and a basis of (technocratic) authority therein. However, controversies and frictions have remained regarding the question whether technocratic authority should prevail merely in the context of scientific debate, or should stretch more broadly to justify political decisions. In light of the politically salient nature of pandemic emergencies, the tension between scientific and legal/political values cannot be overemphasized, and technical expertise should not stand as the sole justification for the WHO's decisions. A member-driven international pandemic lawmaking under the framework convention model, such as the Framework Convention on Tobacco Control, supplemented by proper mechanisms to ensure civil inclusiveness and public reason, presents a potential balance between technocratic and democratic decision-making and better safeguards transparency, legitimacy, accountability.

We envisage the future of international pandemic lawmaking to premise not on mere bureaucratic influences of an international organization, but on a shared arena of stakeholder access, deliberation, and decision-making. A member-driven international pandemic lawmaking in general, and a framework convention approach in particular, promise this vision of global pandemic governance.

The authors would like to thank Prof. Chien-Huei Wu for offering his insights in the process of writing this piece.

### 20. Why We Need a Transformative Right-to-Health Pandemic Treaty Now

Martín Hevia and Ximena Benavides

October 27, 2021

Acknowledging what went wrong during the COVID-19 pandemic is crucial to any pandemic lawmaking efforts. Chief among these concerns should be the centrality of human rights to global health security.

Health systems that <u>lack universality and inclusivity</u> will always fall short on disease surveillance, detection, and response during health emergencies, at the risk of not reaching all populations. The risk of exclusion exceeds national borders. Regional and global health governance favor the 'competition of a few' over (formal) solidarity, which explains why some of the small number of international collaborative initiatives aiming to reach the poorest countries during the pandemic are falling short.

Nonetheless, human rights remain at the periphery of the global health security conversation and the pandemic treaty debate.

Following the call of dozens of world leaders for a new treaty or another legally binding instrument to strengthen pandemic preparedness and response, the World Health Assembly will convene a special session in November 2021 to consider a new binding agreement that could address key failings in the COVID-19 response, including insufficient international cooperation to implement the International Health Regulations' (2005) public health capacities. Such an initiative should also serve as the longawaited international policy-making window

to address our health systems' deep structural problems.

How can a pandemic treaty positively transform our health systems? In this contribution, we outline four core strategies.

1. First and foremost, we ought to relocate the right to the highest attainable standard of health to the center of the post-COVID-19 global health architecture.

Even before the current pandemic, a group of civil society organizations, global health leaders, and academics advocated for a Framework Convention on Global Health (FCGH) that can strengthen our health systems and address the day-to-day indignities and inequities that national and global health systems exhibit. In fact, in 2016, Ban Ki-Moon, then UN General Secretary, called for action by "encourag[ing] the international community to consider and recognize the value of a comprehensive framework convention on global health."

We must advance the right-to-health principles of equitable access, accountability, and participation through global and national programs of action with health equity incentives and action-oriented roadmaps that factor in the SDH. The goal is to fortify public trust that can ensure broad compliance with public-health measures, for example, to reduce vaccination hesitancy. This can be achieved, for instance, by including the appropriate mechanisms for the community to

set priorities and participate in decisionmaking processes for public health policies. In turn, accountability would establish the duty of disclosure of contracts, budgets, and criteria for the allocation of health resources.

- 2. A pandemic instrument should contribute to health, financial, and human capacity through a national and international funding framework that can ensure sufficient and efficient spending and strategies to overcome implementation shortcomings.
- 3. Following the example of international, legally binding treaties such as the Paris Agreement, a pandemic instrument should set coordinated, concrete commitments, and impact assessments to help countries improve their health systems and adjust national policies that affect the health of their own populations and beyond borders, particularly of those most vulnerable and marginalized.
- 4. Lastly, this instrument should promote the right to health in the private sector by establishing standards that ensure that companies do not undermine the right to health nationally or abroad; that is, to enforce the <u>UN Guiding Principles</u> on Business and Human Rights with respect to the right to health.

Why do we need a treaty or another binding legal instrument to channel such transformations? To be clear, an international legally binding instrument is not indispensable in order for health stakeholders to collaborate and prepare for future pandemics. Nations can cooperate with each other and make key joint decisions as they have in the past to overcome global crises.

However, this has clearly not been the way most countries have conducted themselves

with respect to procurement of <u>vaccines</u>, medical protective equipment, and <u>COVID-19</u> <u>tests</u>, as well as with respect to sharing intellectual property on <u>vaccine technology</u>.

As the pandemic continues to reshape the politics and economies of many countries and challenges multilateralism, a more critical approach to health governance and speedy, scaled response from *all* political leaders is needed. In this context, it is clear an international lawmaking effort is justified.

Further, at a time when nationalist populism threatens global cooperation, international lawmaking efforts promise to reinforce the World Health Organization's independent monitoring power and unify a broader and actively involved supportive constituency — including experienced organizations and advocacy groups who are trusted and have a track record of success in promoting health worldwide. A recent good precedent is the Framework Convention on Tobacco Control, where the WHO exercised its constitutional treaty-making power by consensus.

We are witnessing an extraordinary moment in history that urges leaders, international health organizations, global health advocates, the private sector, and the civil society to have a truthful conversation on how to transform our health systems through a health justice framework. The special session of the WHA is an opportunity to empower and engage with a larger constituency to lead deep reforms in global health governance. By agreeing on a set of standards on the right to health, we can initiate the process of transforming the nature of our health systems while reinvigorating global health security, institutions, and governance.

#### 21. Pandemics without Borders?

#### Reconsidering Territoriality in Pandemic Preparedness and Response Instruments

Raphael Oidtmann

October 28, 2021

The COVID-19 pandemic has (yet again) disclosed that, in contemporary international law, the notion of borders resembles a distinct emanation of legal fiction, i.e. 'something assumed in law to be fact irrespective of the truth or accuracy of that assumption'. This characterization of international borders holds particularly true with a view towards managing, containing, and countering the spread of highly contagious pathogens: especially in the context of responding to the global COVID-19 pandemic, it has hence become apparent that the traditional conception of borders as physical frontiers has been rendered somewhat moot. On the contrary, the pandemic experience has proven that a more flexible, fluid, and functional understanding of (international) borders might be warranted, also with a view towards (re-)conceptualizing international health law.

The insinuated conceptual realignment of borders in international (health) law hence requires scholars and practitioners relinquish the hitherto applied focus on territoriality. The classical reading has thus perceived borders primarily in physical terms, i.e. construed as rather static lines of division between delimitable entities with defined points of entry, such as harbours or airports, where selected border measures might be implemented. This reductionist sympathy of borders as stable physical frontiers, however, neglects their multi-dimensional and complex character, various instances in which borders have proven rather porous and fragile, as well as the multiple ways in which borders 'are not necessarily where they are meant to be according to the conventional inside/outside model' (Vaughan-Williams 2008: 63). While we ought to take note of certain sui generis cases in which geographically determined borders

are (still) synonymous with contemporarily applicable borders (such as, inter alia, in the case of Australia), it is thus about time to thoroughly re-examine and, contingently, reconceptualize the notion of international borders for the purposes of pandemic preparedness and response.

When the Special Session of the World Health Assembly will gather in November 2021 to 'consider developing a WHO convention, agreement or other international instrument on pandemic preparedness and response', it therefore might wish to re-examine the manifold effects that have been caused by the imposition of border measures, also during the COVID-19 pandemic, and to ponder contingent avenues to improve the international community's responsiveness towards future pandemic outbreaks. In deliberating a future international treaty or other instrument, this contribution posits, the World Assembly should thus refrain from further designating border action as 'additional health measures' in the meaning of Article 43(1) of the 2005 International Health Regulations, thereby opening a contingent strategic space, which might be unilaterally embellished by single States. Rather, it is suggested here that any future international treaty or instrument should re-emphasise a return to the original 2005 IHR framework's overall alignment, which put particular emphasis on international cooperation in fighting globally spreading diseases, including by engaging complying) with the quasi-compulsory reporting mechanism under Article 6 2005 IHR. Rather than allowing for States to impose unilateral measures, including such unfolding their effects immediately at the border. While it is hence acknowledged that single States that have imposed different kinds of border

measures, it remains unclear whether and to what extent positive developments, e.g. a decrease of infections or mortality rates, might be directly attributable to the imposition of border measures. Beyond that, this insinuated re-orientation would constitute an important step towards mitigating one of the most farreaching conceptual flaws inherent in the 2005 IHR, namely that – despite the WHO's overall preference for enhanced multilateralism - it maintained а discreet, vet formative 'Westphalian' (Fidler 2003: 485) element, allowing States to impose unilateral border measures, including border closures, under the heading of Article 43 2005 IHR in conjunction with Article 3(4) 2005 IHR, the latter highlighting States' 'sovereign right[s] to legislate and to implement legislation in pursuance of their health policies'.

Why is that necessary, one could ask? Well, if COVID-19 has taught us one thing, it is that pathogens do not heed to human-imposed borders, neither domestically internationally. This fact protrudes even more in an ever more globalized world with intercontinental flights, open-border regional economic areas, and overall increased human mobility and interaction. Notwithstanding that selected sanitary measures implemented at defined points of entry - for example, compulsory testing regimes at airports or imposed quarantine measures – have crystallized as useful early-warning instruments aiding in managing disease outbreaks, our previous (legal) understanding

of international borders has proven to be rather obstructive: the observed renaissance of States imposing unilateral border measures as a means to counter the spread of COVID-19, including the closure of borders, has caused wide-spread and detrimental ramifications, inter alia for international trade and commerce, for the maintenance of international supply chains, as well as for human mobility (including professionals) - not to mention profound human rights-related challenges, including with a view to refugees being denied entry at the border. While acknowledging certain isolated successes in limiting the spread of inter alia COVID-19, any future international treaty instrument pandemic or on preparedness and response should thus from further perpetuating understanding of international borders that is based considerations primarily on territoriality - rather, it should ensure that borders are no longer a constitutive element determining the international community's effort of fighting the spread of dangerous diseases.

This contribution is based on a chapter drafted for the 2020 edition of the Centre for Studies and Research at The Hague Academy of International Law on the topic of 'Epidemics and International Law', forthcoming with Brill Publishers.

### 22. Decolonizing the Pandemic Treaty Through Vaccine Equity

Tlaleng Mofokeng, Daniel Wainstock, and Renzo Guinto

October 29, 2021

In recent years, there have been growing calls to "decolonize" the field of global health. Global health traces its roots back to colonial medicine when old empires sought to address

tropical diseases which, if not controlled, could be brought by colonizers back home.

Today, many countries in the Global South may have already been liberated from their

colonizers, but the colonial behavior of global health continues to manifest in policies, funding, research, and operations.

Unlike the tropical diseases of the past, SARS-CoV-2 has affected rich and poor countries alike, but the tools for <u>putting this pandemic under control</u> — most notably vaccines — remain unevenly distributed across the world. As of <u>October 27, 2021</u>, 63.5% of individuals in high-income countries have been vaccinated with at least one shot of the COVID-19 vaccine. Meanwhile, in low-income countries, only 4.8% of the population has been vaccinated with at least one dose.

To make sure that COVID-19 is the last pandemic of its kind, the international community is considering the creation of <u>a</u> <u>new pandemic treaty</u>. The goal of such a legal instrument is to enhance the world's capacity to predict, prevent, detect, assess, and respond to future disease outbreaks.

This treaty cannot become another agent of the perpetuation of global health's coloniality. One of the ways to "decolonize" the treaty is to ensure that vaccine equity is at its very core.

There is still an opportunity to achieve vaccine equity for this current crisis, but cementing it in a pandemic treaty will ensure that this goal remains should another pandemic emerge in the future.

### Promoting vaccine equity between and within countries

Vaccine inequity is occurring between and within countries during the COVID-19 pandemic. A future pandemic treaty must ensure this does not happen again.

In order to ensure vaccine equity globally, actions must be taken through international cooperation and assistance. A <u>statement</u> of the UN Committee on Economic, Social, and Cultural Rights emphasizes this imperative. International cooperation with respect to

vaccines is vital because many low- and middle-income countries (LMICs) do not have the financial resources to guarantee the vaccination of their population. According to the United Nations Development Program (UNDP), low-income countries have to increase their health care spending by around 56% to afford to immunize 70% of their citizens.

To ensure that vaccine equity exists not only between countries, but also within them, it is crucial to uphold the principle of non-discrimination. As <u>noted</u> by the UN Special Rapporteurs on the human rights of migrants and on the right to health:

"In times of crisis, the focus should be given to international solidarity, equality, and inclusiveness. We call on world leaders to refrain from discriminatory discourses that may lead to the exclusion of certain groups (...). The prioritization of vaccines within countries should include all those who qualify under a priority group, regardless of who they are."

#### Reforming intellectual property rights

The TRIPS Agreement, which establishes global intellectual property standards, has caused an adverse impact on the availability of vaccines. Therefore, the UN Committee on Economic, Social, and Cultural Rights argues that States should use, when necessary, all the flexibilities of the Agreement to ensure universal access to vaccination.

The Doha Declaration, enacted in 2001, attempts to address global inequities stemming from intellectual property protections by allowing countries to grant compulsory licenses for the production of pharmaceuticals for international exports. However, the Doha Declaration has not been capable of ensuring vaccine equity during the pandemic. Accordingly, current delegations of India and South Africa, cosponsored by many developing countries, submitted to the WTO TRIPS Council a proposal for a temporary TRIPS waiver in response to COVID-19. The World Trade Organization (WTO) members should endorse the waiver proposal, which will expand licensing agreements and facilitate technology transfer.

Another vital measure to promote vaccine equity is building vaccine manufacturing capacity in the Global South, as argued by The Independent Panel. The African continent, for instance, has less than 1% of the world's vaccine manufacturing capabilities. To address this issue, the World Health Organization (WHO) created the COVID-19 Technology Access Pool (C-TAP), a platform for developers of COVID-19 vaccines and other health products; which enable them to voluntarily share their scientific knowledge, know-how, and intellectual property rights with manufacturers, especially from LMICs.

Though the "paragraph 6 decision" regarding the Doha Declaration already addressed the issue of manufacturing capacity in 2003, it has not effectively solved the problem. In light of this, the UN High-Level Panel on Access to Medicines recommended that WTO Members should revise the decision to find a solution that enables expedient exports of pharmaceutical products produced under compulsory licenses. The pandemic treaty can incorporate this revision to allow accelerated vaccine production and distribution in the case of future pandemics.

#### Reshaping the COVAX Facility

The <u>COVAX Facility</u> was created to avoid vaccine monopoly by wealthy countries, as what <u>happened during the swine flu pandemic</u>. Still, during the COVID-19 pandemic, the consortium has faced the drastic consequences of "<u>vaccine nationalism</u>." For example, the <u>U.K.</u>, <u>U.S.</u>, and <u>Israel</u> have

decided to roll out booster shots in times of vaccine scarcity, when doses are much needed by COVAX for developing countries. Moreover, the lack of inclusive governance, little financial support, poor transparency, and supply constraints have <a href="mailto:impaired COVAX's capacity">impaired COVAX's capacity</a> to promote global vaccine equity.

Therefore, the COVAX Facility should increase transparency by publishing contracts and procurement prices. Moreover, stakeholders must monitor commitments by suppliers to reducing profit through third-party audits, the results of which must be publicly shared. Accountability mechanisms are also imperative to ensure the facility's effective functioning.

Given COVAX's supply shortages, the WHO should consider supporting other actors as well, such as the African Union Vaccine Acquisition Task Team (AVATT) — an initiative that aims to provide access to COVID-19 vaccines for Africa. These reform measures for reshaping COVAX must be taken into account by a pandemic treaty to ensure a sustainable global supply of vaccines during future pandemics.

#### Decolonizing starts with vaccines

There surely are many other aspects of the pandemic response that will need to be reformed and "decolonized" — for instance, pandemic policy and guideline development, knowledge and information sharing, and global health financing flows. But putting vaccine equity at the center of a pandemic treaty will already be a huge step towards global health's decolonization.

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# 23. ¿Quién va a pagar el COVID-29? (O quién va a pagar para que no haya) Sebastián Guidi y Nahuel Maisley

1 noviembre 2021

Las pandemias tienen costos muy tangibles. Cuando aparecen y se extienden, estos costos son obvios y dramáticos — la gente se enferma y muere, las empresas quiebran, los niños y niñas no pueden ir a la escuela. Y cuando no aparecen, probablemente sea porque tomamos medidas extremadamente costosas para prevenirlas.

Estos costos son inevitablemente distribuidos — por acción u omisión — por el derecho internacional. Ahora que la comunidad internacional comienza a discutir un nuevo tratado pandémico, complementario al Reglamento Sanitario Internacional, es importante enfatizar que cualquier tratado que no tenga en cuenta esta distribución de costos se quedará corto como solución aceptable.

Tomemos el COVID-19 como ejemplo. Al momento de escribir estas líneas, América Latina es probablemente la región más duramente castigada por la pandemia en prácticamente cualquier dimensión. El PBI de la región cayó en 2020 un 3% más que el del resto del mundo (llegando a un terrible 7%) y, a mayo de 2021, había sufrido más decesos per capita que cualquier otra región en el mundo: de cada diez personas fallecidas por COVID en el mundo, tres murieron en América Latina. Más de 22 millones de personas cayeron en la pobreza. América Latina es, además, la región del mundo con cierres de escuelas más prolongados: pese a que la región alberga solamente al 6% de la población mundial, contiene al 60% de los niños que perdieron un año entero de escolarización.

Adicionalmente, y tal vez de modo paradójico, si un nuevo marco normativo global se toma seriamente la prevención de las pandemias, la región que fue más golpeada por el COVID-19 podría ser también la más duramente

castigada por las medidas tomadas para la prevención de nuevas enfermedades. Los costos de detener la deforestación y reducir el consumo de carne (señaladas como las medidas más efectivas para prevenir futuras enfermedades zoonóticas) representarían una carga desproporcionada para América Latina, la región que contiene a la selva más grande del mundo y que tiene la mayor tasa de ganado per cápita del mundo.

Una pregunta clave, entonces, es quién debe pagar los costos de una pandemia — e, idealmente, los de su prevención. Preliminarmente, el derecho internacional ofrece tres líneas argumentales para resolver este intríngulis.

La primera está basada en la <u>solidaridad</u>. Según los <u>artículos 55 y 56 de la Carta de las Naciones</u> <u>Unidas</u>, los estados tienen la obligación de "tomar medidas conjunta o separadamente" para encontrar soluciones a "problemas internacionales de carácter económico, social y sanitario" de modo tal de promover "niveles de vida más elevados, trabajo permanente para todos, y condiciones de progreso y desarrollo económico y social" teniendo en consideración la <u>"igualdad de derechos de hombres y mujeres y de las naciones grandes y pequeñas"</u>.

Múltiples líderes globales han ensavado este argumento en relación con el COVID-19: en los foros internacionales, muchas han insistido en una "aproximación a la crisis cooperativa, global y basada en los derechos humanos" con "unidad y solidaridad". La rápidamente frustraría estas esperanzas. Por ejemplo, mientras los países desarrollados han acumulado una cantidad de vacunas ampliamente superior a las que necesitan, los países más pobres continúan luchando por proteger incluso a las poblaciones más vulnerables.

La segunda respuesta se basa en la culpabilidad. En derecho internacional, los estados tienen una obligación general de no dañarse unos a otros — y una pandemia ciertamente daña a los estados y sus ciudadanos. Si se demostrara que algún estado causó la pandemia de modo ilícito, podría ser llamado a dar respuestas e incluso a indemnizar el daño causado. Al menos, este fue el razonamiento de líderes nacionalistas alrededor del mundo, con Donald Trump a la cabeza, quien en marzo de 2020 anunció que demandaría a China por "desatar esta plaga" sobre la humanidad". Como mostramos en otro texto, aun si este tipo de atribución es motivada por sentimientos nacionalistas o por la búsqueda de un chivo expiatorio, también puede ser reconstruida como un argumento que implica profundos juicios distributivos. De todos modos, en el caso del COVID-19, esta estrategia fue rápidamente abandonada ante insuperables obstáculos jurisdiccionales.

El tercer camino está basado, en última instancia, en la suerte bruta. Dado que "no pueden presumirse restricciones a la independencia de los estados", y no habiendo un acuerdo en contrario, los estados no tienen responsabilidad jurídica por aquellos que están fuera de sus fronteras nacionales. Sin importar su capacidad de pagar o qué tan severos sean los efectos de una pandemia, tiene cada estado únicamente responsabilidad de proteger a sus propios nacionales. Los costos de una pandemia, entonces, según esta aproximación, quedan donde caigan por fortuna.

En el caso del COVID-19, la respuesta de la comunidad internacional fue paradójica. Si bien la mayoría de los actores políticos y sociales abrazaron discursivamente (y, uno podría pensar, sinceramente) la primera o la segunda opción, la realidad nos decepcionó y nos dejó con la tercera. De hecho, y si bien los principios de derecho internacional permitían

soluciones alternativas, las regulaciones realmente existentes y la inercia institucional no permitieron el tipo de redistribución ambiciosa necesaria para una distribución de costos más reflexiva — incluso a pesar de que los propios líderes globales se comprometieron a hacerlo.

Uno podría haber esperado una solución explícita a este desafío, una que distribuyera los costos de modo equitativo, en el instrumento más importante con el que cuenta el derecho internacional para lidiar con Reglamento Sanitario pandemias: el Internacional. Sin embargo, el Reglamento no toma posición frente a estas opciones sustantivas; en cambio, se limita a establecer obligaciones procedimentales (con un impacto distributivo mínimo). Este foco en los procedimientos es entendible. Como explica Martti Koskenniemi en otro contexto, los estados a veces recurren a estas soluciones porque "el acuerdo en cuestiones de derecho sustantivo requiere más consenso cuestiones de valoraciones políticas que el acuerdo en cuestiones procedimentales. Las soluciones procedimentales, combinadas con invocaciones genéricas a ponderaciones justas, no perjudican la política sustantiva de ningún estado".

Por <u>lo que sabemos</u>, el nuevo tratado sobre pandemias probablemente replicará este énfasis en los procedimientos. Al igual que el RSI, podría incluir obligaciones (aumentadas) de detección temprana, de notificación, de transferencia de <u>información y de cooperación</u> amplia.

Esto, sin embargo, dejaría abiertas las cuestiones <u>sustantivas</u> necesarias para una <u>distribución deliberada</u> de los costos de las pandemias. ¿Quién deberá detener la deforestación en su territorio (y quién, si es que alguien debe hacerlo, compensará por la falta de desarrollo económico que eso podría conllevar)? ¿Quién deberá modificar sus patrones de consumo de comida para permitir la producción más segura de carne? ¿Deberían

los estados ricos pagar y distribuir vacunas y medicación (aun mientras sus propias poblaciones no estén completamente protegidas)? Y si nada de todo esto funciona, ¿deberían los costos económicos y sociales de las pandemias ser mitigados por aquellos que menos las han sufrido?

Estas preguntas sobre la distribución de los costos de las pandemias son inevitables, pero también son prácticamente intratables. Muy probablemente, ningún tratado sobre pandemias podrá zanjar, ni siquiera de modo mínimo, estas complejas cuestiones sustantivas.

Pero si los estados realmente desean resolver significativamente los asuntos clave que invariablemente surgirán en relación a pandemias futuras, las cuestiones relacionadas con la distribución de costos deben ser afrontadas con franqueza y rigor. No poder llegar a un consenso completo en este preciso momento no es lo mismo que no poder hacer nada al respecto.

En primer lugar, y de manera central, los estados podrían rechazar explícitamente la situación actual, manifiestamente injusta, en la cual los costos quedan, por defecto, donde caen. Segundo, podrían esbozar los criterios normativos amplios que podrían guiar su distribución en el futuro. Y tercero, podrían

crear mecanismos institucionales adecuados — con participación de la sociedad civil, transparencia, y representación adecuada de todas las voces — para permitir y fomentar un diálogo continuo y global sobre estas cuestiones sustantivas, que pueda obtener respuestas que reflejen las opiniones e intereses de la gente de todo el mundo.

Estas conversaciones serán difíciles, pero su alternativa es peor. Si no las tenemos, la respuesta a un eventual COVID-29 podrá ser más ordenada y cortés, pero, en lo fundamental, será igual de injusta.

Esta entrada de blog es consecuencia de una agenda de investigación que comenzó con un artículo publicado este año: "Who Should Pay for COVID-19? The Inescapable Normativity of International Law." (96 NYU Law Review). En este artículo, argumentamos que la discusión generalizada sobre la posibilidad de demandar a China por la pandemia de COVID-19 refleja una incomodidad respecto de la forma en que el derecho internacional distribuyó los costos de la pandemia. Cualquier intención de resolver esta incomodidad lleva a una compleja discusión normativa sobre la distribución de los costos de la pandemia.

## 24. The Covid-19 Pandemic, the Failure of the Binary PHEIC Declaration System, and the Need for Reform

Ilja Richard Pavone

November 2, 2021

The COVID-19 pandemic has raised unprecedented challenges for the global health framework and its long-term consequences are not yet in full sight. The legal and institutional regime aimed at preventing and controlling the spread of infectious

diseases, grounded on the International Health Regulations (IHR) was heavily criticized.

The alarm mechanism based on the declaration of Public Health Emergency of International Concern (PHEIC), in particular, has been <u>severely tested</u>. A PHEIC is an extraordinary event that constitutes a

potential public health risk through the international spread of a disease outbreak. The WHO Director-General bases his decision to 'ring the bell' upon the technical advice of an Emergency Committee (EC) carrying out "an assessment of the risk to human health, of the risk of international spread, and of the risk of interference with international traffic".

A PHEIC, then, is declared only when an event is already sufficiently acute and has started to spread internationally. It is not an early warning, but a formal alert, and in the case of COVID-19 it was issued with extreme delay only on 30 January 2020, (one month after notification of early cases by the Chinese government), after Beijing had already adopted quarantine measures around the city of Wuhan, and draconian measures to curb the spread of the disease in the country had been announced.

It is not yet clear why the EC, which was summoned on 22 and 23 January 2020, decided that it was 'too early to declare a PHEIC'. It has been arguably a problem of political pressure by the Chinese delegate, as well as of incapacity of the EC's members. More probably, due to the lack of precise information by the Chinese government on the real extent of the disease outbreak, they opted for a conservative approach, well aware of the economic and political consequences of a PHEIC declaration for the concerned State. In general terms, one of the problems lies in the rigid binary nature of a PHEIC – that is declared or not – and does not envisage intermediate levels of alert.

In the Declaration of 30 January 2020, the DG showed awareness about this problem, hoping that the "WHO should continue to explore the advisability of creating an intermediate level of alert between the binary possibilities of PHEIC or no PHEIC, in a way that does *not require reopening negotiations* on the text of the IHR (2005)." He recommended developing a New Alert and Response Notice (WARN) system that should provide adequate information to

the WHO Member States of the actions required to tackle an event that has not yet reached the threshold of a PHEIC, but may nonetheless require a coordinated response. It should take the form of a notice containing a WHO risk assessment to be shared amongst the Member States, and it should detail the specific public health actions that are recommended to prevent cross-border transmission. Given that the WHO has provided recommendations even when it has not declared PHEIC, the legal added value of this WARN system is not however clear

The need of a reform was then reiterated in a <u>WHO's Interim Report</u>, which proposed an intermediate level of alert, a sort of 'yellow light' as an initial warning signal (Para. 32).

This kind of proposal is not a novelty, since it was already recommended in a previous document on the <u>response to the Ebola outbreak</u> in Western Africa (although it was never endorsed by the WHO Member States). The Panel recommended "the possibility of an intermediate level that would alert and engage the wider international community at an earlier stage in a health crisis. This could facilitate preparedness, preventive action, and dedication of resources, which could avert an escalation of the situation".

This kind of reform, that could be labelled as a 'traffic light mechanism', or 'tiered alert system', to be really functional should bypass the <u>risk based approach</u> upon which the assessment of the DG is conducted. It would imply to overtake the classic <u>reluctance of the WHO and the EC to impose travel and trade restrictions</u> before a risk assessment is carried out, since they are usually considered as ineffective and counterproductive.

Even though the various proposals envisioned different tiers –ranging from only a yellow light before a PHEIC to a <u>flowchart with 5 levels of alarm</u> – they all have the goal of encouraging early reporting of and response to, potentially serious disease outbreaks.

Despite the wide range of possibilities, the first problem is, however, how to concretize a potential reform. The easiest solution could imply the negotiation and adoption of an additional protocol amending the IHRs or at least Annex II, and introducing a more nuanced alarm mechanism.

Otherwise, a technical note could provide a specific flowchart to both the EC and the DG, based on a multi-tiered declaration approach; in few words, the DG could be able to recommend specific measures to its Member States even before the formal declaration of a PHEIC.

The necessity to replace the all-or-nothing nature of PHEIC declarations is not a novelty in the academic debate, but in light of the world-wide diffusion of the COVID-19 pandemic it became crucial. Such reform could relaunch the IHR and beef up the role of the WHO in managing future pandemics, but the normative power of a PHEIC declaration should not be overestimated, which is not a

binding act but rather an instrument of governance through information. Indeed, States do not wait for the 'red light' of the WHO to react to a potential epidemic or pandemic, but in view of their own source of information can decide to react earlier if they want. This was witnessed in the early stages of COVID-19, when Vietnam and Taiwan decided to adopt stringent measures well before the end of January.

In conclusion, as underlined by <u>some scholars</u>, a reform of the PHEIC's mechanism would not solve the core issues of the alert and response system behind the IHRs, that do have mainly a political dimension. Indeed, States are reluctant to act in good faith and to share information in case of a disease outbreak, tend not to comply with the DG's temporary recommendations, and have not developed adequate core capacities to respond to disease outbreaks.

# 25. Casualties of Preparedness: Rethinking the Global Health Security Paradigm

Manjari Mahajan

November 3, 2021

The calls for a new pandemic treaty, like the genesis of the International Health Regulations (IHR), have been anchored within a paradigm of "global health security." Before undertaking new projects of international lawmaking, it behooves us to examine this dominant paradigm and assess whether it actually leads to the goal of pandemic preparedness across countries. At stake are the future contours of a global normative, legal and infrastructural machinery and whether its animating logics are historically informed, evidence-driven, and geographically equitable.

The prevailing global health security paradigm was institutionalized in international law through the IHR, a policy centerpiece that was most recently revised in 2005 in response to a series of new infectious diseases including AIDS, SARS, and Ebola. At its foundation, the schema identifies the problem at hand as outbreaks of emerging infectious diseases, which become global security threats as they travel across borders. The focus is very much on *new* and re-emerging infectious diseases, and not ongoing health-related problems in a population. Moreover, this framework is animated by a special anxiety about contagion

from poorer, purportedly primordial and volatile countries in the global South to the North.

The emphases on new infections and preventing their travel from the South to the North have resulted in a politics of control and enforcement that carry with it particular normative and infrastructural demands.

First, it has required that member states invest in building surveillance and reporting systems that allow for rapid reporting of infectious outbreaks to a global machinery. The global health security paradigm has not focused on building national capacities to address existing diseases or overall public health in a population. However, the COVID-19 pandemic has vividly illustrated that making a stark distinction between capacities to address new infectious outbreaks and routine public health is a costly mistake.

Second, the global governance of health security has demanded some ceding of national sovereignty, with member countries required to adhere to a common template of surveillance and reporting systems. States have to put into place a suite of narrow technical and administrative measures for biosafety and biosecurity; a country's pandemic preparedness has been judged based on their having met these <u>universal benchmarks</u>. This has produced a disproportionate burden on poorer countries.

Especially from the point of view of a developing-country government, it might be less effective to use limited resources to add narrow technical capacities to feed a global machinery of surveillance, than to invest in overall scientific infrastructure that is integrated into a national system of research and innovation reflecting local needs. The one-size-fits-all benchmarks set by global managers has disallowed consideration of domestic imperatives and political judgment about resource allocation.

Moreover, one of the striking lessons of COVID-19 has been that countries that have provided relatively sustained and competent responses to the pandemic have not followed any single template. Successful public health action has been enabled by diverse assemblages of institutions, policies, historical legacies, and socioeconomic resources that have been necessarily highly contextual to each country. These heterogenous responses belie the convenient notion that it is possible or necessary to have neat templates of preparedness that can be applied uniformly across countries.

Third, much emphasis has been put on individual governments reporting to a larger international machinery. Here, a government's accountability is not to its own people or to achieving particular health outcomes or adhering to national laws. Rather it is conceptualized as a government's capability to assure a global apparatus.

Accountability becomes equated to performative visibility where a government has to frontstage and show its preparedness capacity in a way that can be easily measured by indices and checklists of the global machinery. The privileging of reporting echoes secular trends within global health, where audits of governments and NGOs to donors anchor definitions and procedures accountability. Inevitably such a framework creates perverse incentives for organizations to invest in producing information that can be captured by indicators, often at the cost of more meaningful work.

The limitations of this conceptualization of accountability are vividly illustrated by the fact that before the current pandemic, the United States and the United Kingdom were considered the "most prepared" by multiple global health security indices. Even though both countries tick-marked many of the requisite boxes in the preparedness checklist, they have since had a disastrous track record in managing the pandemic.

Ironically, even as extant accountability measures privilege national reporting to a global machinery, they completely elide any enforceable commitment by the international community to ensure equitable access to technological countermeasures, such as vaccines and medicines. Similarly, this understanding of accountability doesn't include a global commitment to increasing capacity for knowledge and technological development across countries determined by sovereign priorities.

Lessons from history and a commitment to global equity require that our analytical frameworks and ensuing international governance systems move away from the overwhelming focus on centralized reporting and generic templates. Rather they have to include divergent approaches that speak to different countries' historical experiences, social needs, and political imperatives.

Abandoning a universal templatized approach to control and enforcement is a significant challenge for global governance of health, which has long relied on modeling countries on generic templates and metrics, and tick marking through common checklists. Nevertheless, COVID-19 has starkly illustrated the urgent need for more sophisticated narratives and frameworks that embrace complex understandings of health and preparedness. This will undoubtedly require more complex and "messy" analyses; yet it is

necessary — the alternative prevailing global health security paradigm is an emperor without clothes.

As the international community debates a new pandemic treaty or another legal instrument, the history of the last several decades of international health, and the more proximate experiences with COVID-19, should force a reckoning of the limitations and unintended consequences of the dominant global health security paradigm. The lessons do not point to the need for an exclusive and overwhelming surveillance focus on and reporting infrastructure. nor stricter enforcement mechanisms managed by global authorities.

Rather, there is a need for a different conceptualization of global health security that is anchored in frameworks that contextualize health in broader historical narratives and political and social determinants. State social resilience, capacities, economic imperatives, and political culture have to be understood not as ancillary sideshows as much as inextricable determinants of preparedness. Accordingly, the governance of global health must systematically security integrate different kinds of expertise and meaningfully represent states around the world. It must go beyond rhetorical gestures to participation toward a substantive consideration of the complex underpinnings of health and its varied national trajectories.

### 26. Brújula jurídica de un acuerdo sanitario: de la cooperación a la solidaridad

Guillermo E. Estrada Adán

3 noviembre 2021

El texto propone la incorporación de la solidaridad en un nuevo acuerdo sanitario como brújula jurídica de las normas internacionales que permita afrontar las distintas etapas de una pandemia. El punto de

partida es enfatizar el agotamiento de un modelo de gobernanza sanitaria, el de la Organización Mundial de la Salud, basado en la cooperación entre Estados; el puerto de llegada sería un acuerdo que responsabilice a todos los Estados frente al goce de los derechos de las personas.

#### El fracaso de la cooperación estatal.

Eyal Benvenisti sostiene que, mas allá de las críticas a la capacidad de reacción que la Organización Mundial de la Salud -OMS- ha mostrado con la pandemia de la COVID-19, el problema fundamental es la limitación estructural de una organización internacional basada sobre todo en la cooperación científica. La armadura de la OMS descansa en un modelo de alto nivel de colaboración que podría ser exitoso solamente cuando los Estados logran alinear sus intereses. Si ese objetivo común no llega, la cooperación es irrealizable. En los últimos meses, los Estados han gestionado la pandemia, incluida la vacunación, según intereses individuales, en ocasiones electorales, políticos o económicos, pero prácticamente en ningún caso bajo una visión colectiva.

Dicha actitud puede comprenderse, al menos en el discurso, porque los Estados, bajo una aproximación westfaliana, son igualmente soberanos y, por tanto, podrían desplegar un mismo papel en el escenario internacional. Un análisis más detenido ha evidenciado que, en realidad, es la geografía económica y hegemónica la que determina las decisiones importantes (estados de emergencia, distribución de vacunas) y no la igual voz de los Estados ni menos aún la protección de los derechos o los contextos de distintas poblaciones. En el mejor de los casos, el disfrute de los derechos es un asunto que se resuelve bajo las nociones tradicionales de frontera y nacionalidad: primero los nacionales y dentro del territorio estatal. La coordinación solamente es eficaz si los Estados tienen los mismos objetivos; lo contrario produce acciones en distintas direcciones y no siempre homogéneas.

En ese planteamiento, el Norte y Sur globales permanecen como elementos determinantes para describir y comprender la actuación política y jurídica estatal frente a la pandemia por COVID 19 y, de no incorporarse brújulas que orienten la dirección e implementación de las pretendidas nuevas normas internacionales, corremos el peligro de que esos mismos elementos definan también las rutas de salida a las pandemias, la presente y las futuras. Haría falta moverse de ese esquema a otro de mayor responsabilidad jurídica colectiva: del modelo de cooperación internacional al de solidaridad global.

#### La solidaridad como herramienta jurídica.

Al interpretar el derecho, esto es, al dotar de significado un término, así como al momento de exigir obligaciones jurídicas, la solidaridad tendría que orientar las decisiones jurídicas y políticas. La solidaridad ha sido un vocablo usado con frecuencia en el derecho privado que facilita la identificación de todos los deudores en el mismo nivel del cumplimiento de una determinada obligación y, al mismo tiempo, enfatiza una referencia ética colectiva.

En el derecho público, o más aún, en el derecho internacional, salvo referencias aisladas y débiles, por ejemplo en la Declaración de principios sobre solidaridad y cooperación interamericanas de 1936, la noción de solidaridad ha sido poco utilizada, frente a vocablos como sobre todo cooperación o colaboración. En la Carta de las Naciones Unidas el vocablo solidaridad no aparece en ninguna ocasión mientras que en la Carta de la OEA existen al menos 8 referencias desde el preámbulo hasta menciones relacionadas con la seguridad colectiva de la región. No hay, sin embargo, una definición esclarecedora ni ocupa un lugar importante en el desarrollo de otros principios u obligaciones. La Constitución de la OMS tampoco refiere el vocablo.

La solidaridad puesta en un nuevo acuerdo ofrecería una visión que incluye el contexto de los más desaventajados en la toma de decisiones. Estaría anclada, primero, a una manera de entender las obligaciones jurídicas,

para que los Estados prefieran el beneficio colectivo al individual. Es decir, supone que, frente a las acciones que implica la gestión de pandemias -cuarentenas, aislamientos, vacunación, restricciones de derechos-, el argumento decisivo sea uno de alcance global y no uno particular. Frente a distintos posibles significados normativos, determinante para las decisiones estatales, las de actores no incluidas estatales, las organizaciones supraestatales, la solidaridad sería significado vencedor y, por tanto, se ejecutaría una restricción de derechos o una distribución de insumos, entre otros, a partir de criterios globales.

Estaría anclada, también, a la noción de las obligaciones *erga omnes*, donde un Estado puede exigir de otro el cumplimiento de una conducta incluso cuando no se considere Estado lesionado. Esta institución jurídica, de perfeccionamiento reciente, generaría puentes procesales para identificar a los Estados que lejos de mirar beneficios colectivos procuran solamente los propios. La salud humana y su protección ya ha alcanzado

el estatus de derecho humano en distintos acuerdos con vocación universal o regional.

El preámbulo o un apartado especial de un novedoso tratado internacional orientado a hacer frente a pandemias, o incluso un nuevo diseño de una organización de gobernanza sanitaria global, dentro del articulado, si desarrolla la noción de solidaridad, protegería mejor los derechos de los otros sin anteponer los intereses estatales — individuales. La propuesta de este ensayo es que el vocablo solidaridad sea protagónico en un nuevo acuerdo internacional.

La solidaridad, como parámetro de interpretación y aplicación del derecho, va más allá del contorno delineado por la gobernanza sanitaria. Constituye más un valor colectivo, aplicable siempre que se aspire a un derecho internacional basado en la equidad. La oportunidad de una revisión al modelo sanitario mundial, es una oportunidad de ubicar a las personas físicas, las de esta y otras generaciones, en el centro de la protección jurídica.

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