REFORMING GLOBAL HEALTH LAW THE WORLD HEALTH ORGANIZATION, THE PANDEMIC TREATY AND THE INTERNATIONAL HEALTH REGULATIONS: CHALLENGES AND OPPORTUNITIES

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CLOSING THE COVID-19 GAP: GOVERNANCE, POWER, RULES, FINANCING

- Need for better governance, WHO and beyond - new bodies (Global Pandemic Board/Council) and system approach
- Questions of power and control, G20/G7 club approach versus WHO/UN – role and leadership of regional organizations
- Financing: search for a new model to fund national capacities and global public goods – use existing institutions or create new fund? New Pandemic Fund
- Crisis of equity and solidarity, in particular access to medical countermeasures, technology transfer. Search for sustainable solution. ACT-A and COVAX
- Balancing of public versus private authority – power of industry and philanthropies
- Human rights – safeguarding dignity and livelihood. Reaction of human rights mechanisms.
- Looking upstream and ddressing prevention of zoonotic diseases: "One Health" and the "Quadripartite"

CRISES AND INTERNATIONAL LAW

- Crises as the "epistemic unit" of international law?
- Hilary Charlesworth, "International law: a discipline of crisis" (2002)
- Critique: political bias, selectivity of crucial facts, thin and simplified assessment and vocabulary avoiding larger picture and justifying status quo, accepting forms of intervention as inevitable and good, hiding structural problems that are at the roots of the crises.
- Global health law prone to narrative of crises: epidemics, HIV-AIDS, pandemics etc
- Counternarrative – human rights and dignity and structural problems creating vulnerability to shocks.

LEGAL FRAMING OF THE COVID-19 PANDEMIC

- Was it a crisis? What was the crisis? Only about health? What causes and consequences? Narrative of exceptionalism.
- Which structural problems has COVID-19 confirmed?
- 1) deep inequalities within countries
- 2) deeply inequitable international system
- 3) Flawed and unpredictive national capacities
- 4) Excessive corporate power
- 5) Systemic risk of zoonotic diseases – One Health and environmental drivers
- Successful framing as protection of human health: focus on WHO and path dependency for normative developments.

INTERNATIONAL HEALTH REGULATIONS

- <u>Constitutional basis</u>
- Article 21:"The Health Assembly shall have authority to adopt regulations concerning:
  (a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease…."
- Article 22: "Regulations adopted pursuant to Article 21 shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservations within the period stated in the notice."

MAIN FEATURES OF THE IHR

- Historical legacy of international cooperation for health security. Old system and 2005 revision
- Global instrument: 196 states parties
- Open-ended framework based on "disease", "event", "public health risk", "public health emergency of international concern" and "pandemic emergency"
- Scope: natural, accidental, intentional events. Security and political implications. Globalization of health risks
- Adaptation to different events through cooperative risk assessment and management
- Managerial instrument and joint framework for action and coordination
- Limited scope: preparedness, detection, containment

STATES' OBLIGATIONS

- Cooperation, transparency and good faith – assessment and reporting of events.
- Core capacities: health security is implemented inside a country
- Control measures and their limits, including human rights. Health security at the borders. Routine measures of great importance
- Article 43: states retain the final word but subject to disciplines. Weak WHO's oversight and limited accountability

WHO'S FUNCTIONS AND POWERS

- Surveillance, information, alert, joint risk assessment with states
- Use of non-state information and challenge of dependence on states
- Functioning of the emergency mechanism: public health emergency of international concern. Authority of DG, role of emergency committee
- Temporary and standing recommendations: what is their legal force and effect?
- New functions: facilitating equitable access to health products
- «Grand bargain»: managerial authority versus sovereignty (Article 43)

IMPLEMENTATION OF THE IHR: WHAT IS AN EMERGENCY?

- H1N1 influenza (2009-2010)
- Ebola in West Africa (2014-2016)
- Polio (2014….)
- Tsika (2016)
- Ebola in the DRC (2018-2019)
- COVID-19 (2020-2023)
- Mpox (2022 – 2023)
- What is not an emergency?
- MERS (2012-2013)
- Yellow fever in Africa (2022)

CHALLENGES OF THE IHR

- 1) Unrealistic binary alert and bias towards new diseases in the global south (cf. monkeypox and polio)
- 2) core capacities (intrusive, challenging, overambitious and underfunded?)
- 3) lack of compliance monitoring and accountability mechanisms – soft and voluntary tools
- 4) discretion of states to act without much accountability and unclear limits.
- 5) WHO's deference to states for crucial surveillance and alert functions (the "China syndrome")
- 6) Insufficient incentives and deterrents. No protection for compliance (South Africa and the Omicron variant)
- 7) IHR unfit to coordinate collective response to long emergency?
- 8) Equity and situation of developing countries not reflected in the IHR

IHR AMENDMENT PROCESS – 2022/2024

- Criticism against the IHR and WHO's role in previous crises: low compliance, lack of transparency, lack of compliance mechanism, unrealistic alert structure etc.
- Shared reluctance to address design flaws: don't amend, just better implementation
- USA initiative in January 2022 – strengthen existing framework and increase compliance
- WHA 2022: adoption of "technical amendments" and opening of amendment process. WHA mandate: "targeted amendments"
- Unusual approach: frontloading amendment proposals

THE PROCESS

- More than 300 amendments by more than 100 states
- Broad variety: from clarifications and strengthening of existing approach to ”equity” proposals overlapping with pandemic agreement
- Constitutional question: will they fall under Art. 21?
- IHR review committee and WGIHR – 8 sessions
- Limited transparency but constructive approach: consolidation, complementarity with pandemic agreement, motivation of every proposal
- Parallel process with negotiation of pandemic agreement: overlapping proposals and questions of placement

THE OUTCOME: REALISTIC OR DISAPPOINTING?

- 1) "alert levels": pandemic emergency but no early action;
- 2) National IHR Authority;
- 3) "equity and solidarity" as principles;
- 4) Article 13 etc. – access to health products under WHO's responsibility
- 5) rationalization of health documents (Art. 35)
- 6) Financing (Art. 44 and 44 bis)
- 7) Implementation committee (Art. 54 bis)
- 8) Quicker entry into force of amendments
- 9) more detailed core capacities (Annex 1)

NEXT STEPS

- DG notification triggers entry into force – September 2025
- Risk of rejections and reservations – unfavourable geopolitical moment and unpredictable US position
- Heavy responsibilities for WHO – will it deliver? What are the risks? Politicization of the IHR?
- Building new governance – implementation committee and coordinating financial mechanism
- Stronger state oversight and political approach – need for balance

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THE "PANDEMIC TREATY"

- EU initiative, role of DG Tedros, "friends of the treaty"
- 1) Why do we need a treaty? What is the politics behind it?
- 2) What about the International Health Regulations (IHR) and other instruments and international regimes like trade and intellectual property, transport, biodiversity, wildlife trade?
- 3) what content?
- Ambivalent reactions and political positions. Launch of WHO process: USA initial hostility, Global South skepticism, EU motives. Lack of preliminary discussion and of consensus on purpose, objective and functions. Is there a shared bottom line?
- Choice of WHO as forum – framing complex issue as protection of human health. What are the consequences? What about the UN?

PROS AND CONS OF A TREATY

- Substantive and systemic gaps to fill not addressed by the IHR
- need to generate and channel high level all-of-government commitments that IHR cannot achieve.
- IHR narrow instrument, too technical, it can't excite leaders, low compliance and effectiveness,
- lack of accountability framework, need to ensure enforcement and possibly sanctions.
- Need to focus on deep prevention and long-term response
- Treaty enables "club approach" of countries accepting stronger obligations

WHERE ARE WE NOW?

- A dysfunctional process? Why? What went wrong? Lessons learnt.
- What is the content of the treaty? An ambitious instrument.
- Pending issues: 1) Prevention and One Health; 2) Modalities for tech transfer; 3) pathogen and benefit sharing (PABS); 4) "Peace clause"; 5) Compensation and liability; 6) Compliance mechanism; 7) Subsequent instruments and prospects for a "package"
- Missed deadline of May 2024, aiming at May 2025 – are deadlines useful?
- Sense of stalemate and entrenched positions. Is there still political will? Will Trump 2.0 make a difference?

HOW TO MANAGE COMPLEXITY - EQUITY

- "Equity" as a principle and proxy for political requests (principle 4)
- "Common but differentiated responsibilities" : does it make sense in a pandemic accord?
- Equitable access to countermeasures: experience of ACT-A and COVAX and different approaches – how to commit the industry?
- Transfer of technology and distribution of manufacturing capacities – WHO's role and challenges
- IPR management (article 7): what can a WHO treaty do? Relations with WTO/TRIPS
- Financing (article 19 PA, article 44A IHR) – can WHO become a financing agency? Domestic versus international funding – new funds versus using existing resources (Pandemic Fund)
- Different priorities for north and south: security versus equity - is a package deal possible?

PREVENTION AND ONE HEALTH

- Lesson from COVID-19: growing risk of zoonotic spillover
- 60% human infectious diseases have 'zoonotic origins' - 72% of these have wildlife source
- Wildlife and livestock: habitat shrinking, intensive farming, species mixing, international trade and travel
- PA: Arts 4 (prevention and surveillance) and 5 (One Health approach)
- Agreement in principle, but mutual mistrust and bargaining chip
- OH as conceptual and operational approach but vague and decentralized among national and international agencies. Challenge of operationalization

Relevant international legal instruments

Overall goal	**Reduce risk of infectious disease (re)emergence and spread in humans and animals**			
Context	Environmental governance		Public health governance	
Approach	Deep prevention		Containment	
Stage of intervention	Upstream	Midstream	Downstream	
Focus	Preventing drivers	Preventing events	Detecting, reporting and containing events	
Regulatory target	Drivers of (re)emergence and spread	(Re)emergence (spillover, mutation, outbreak)	Human disease outbreak	Human disease spread
Instruments	International agreements, e.g. on wildlife trade (CITES), climate change (UNFCCC/PA), biological diversity (CBD, Biosafety Protocol), land-use change (CBD,UNCCD), international traffic, population movements, etc	**Regulatory 'blind spot' and role of pandemic agreement** **Quadripartite (WHO, FAO, WOAH, UNEP)** **Soft standards (Codex)**	IHR (2005), including self-assessment and Joint External Evaluation (JEE) WTO General Exceptions, SPS, FTAs	

Source: G. Le Moli et al, The Deep Prevention of Future Pandemics through a One Health Approach: What role for a Pandemic Instrument? (GHC/C-EERNG, June 2022)

IMPLICATIONS FOR OTHER AGREEMENTS SEARCH FOR SYNERGY AND COHERENCE

- **Upstream**: Inclusion of health dimension in environmental agreements, recent development with Kunming-Montreal, UNFCCC COP 29 declaration and CBD COP 16 on biodiversity and health. CITES with potential gap as only conservation instrument
- **Downstream**: role of WTO-SPS in preventing zoonotic diseases, food contamination. SPS science-based and harmonization instrument, crucial role of standard-setting: role of Codex, WOAH and Plant Convention
- Open issue of participation of Quadripartite organizations in PA implementation and resentment at WHO's lack of mandate. How to achieve that? Is a treaty the appropriate instrument?

PATHOGEN AND BENEFIT SHARING

- Central issue in PA negotiations – last trench of ”equity” and perception of leverage for global south. Mutual mistrust and current stalemate. Hollowing out of text and reliance on future instrument. Are the expectations justified?
- Multiple layers of complexity and uncertainty of PA process outcome
- Starting points:
- 1) Evident need to share pathogens for public health purposes – samples and DSI
- 2) Development of scientific practices, networks and repositories
- 3) encroachment of international biodiversity law – complexity, equity, politicization

HOW MUCH DO YOU KNOW ABOUT THE CONVENTION ON BIOLOGICAL DIVERSITY?

- CBD adopted in 1992, quasi-global participation. Framework convention – two protocols: Cartagena on GMO and Nagoya (142 parties) on benefit-sharing
- Rationale: preservation of biodiversity, combating biopiracy, leverage for mega-diverse countries and indigenous people. Public health not part of original design
- Objectives (art. 1): "conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources"
- Principles (art. 15): sovereignty over genetic resources, no firm obligation to share, prior informed consent, mutually agreed terms

LINKAGES BETWEEN CBD AND PATHOGENS

- Definitions: ” "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.”
- "Genetic resources" means genetic material of actual or potential value”
- Indonesia’s 2007 claim and subsequent growing consensus: pathogens fall under CBD
- CBD and Nagoya Protocol: transactional, bilateral approach and incomplete contracts unfit for public health and health crises – risk of chilling effects (influenza)
- WHO’s PIP Framework as first multilateral reaction, but not tested so far
- PA negotiations: tension between sovereignty claims and search for multilateral model

MAIN LEGAL ISSUES
1) CARVE OUT

- Creation of self-contained system carved out from CBD/Nagoya. Art. 4.4 Nagoya: "Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument"
- What criteria for an SII? Will PABS qualify? Who decides? What consequences from determination? What possible outcomes?
- PIP Framework as extant non-binding SII and challenge of integration into PA

2) MANAGEMENT OF DIGITAL SEQUENCE INFORMATION (DSI)

- DSI/GSD not mentioned in CBD and PIP and no official position on inclusion in its scope
- Fundamental differences with physical samples, existing network of databases with own rules, ease of sharing, difficult to track and trace, difficult to link with jurisdiction. Increasing accessibility of technology and increased use in pharma – game changer.
- Search for an ad hoc normative regime and influence on future PA: 1) CBD COP decision 15/9 (2022) on distinctive solution for benefit sharing, multilateral solution, no T&T, search for legal certainty. Decision 16/2 (2024) creating "Cali Fund" for DSI benefit sharing by benefitting sectors. Still work in progress. What implications for PABS?

- Challenge of involvement of private sector: prescribe and regulate or encourage and urge
- How to adapt international law to technically complex and diffuse practices? Risk of chilling effects or ineffectiveness
- How to distribute obligations to provide benefits? How to create incentives and ? Is the Cali Fund the right answer? Is there a risk of duplication with PABS?
- What are the possible models? What precedents? FAO treaty on plant genetic resources for food and agriculture, PIP Framework, BBNJ

TECHNOLOGY TRANSFER

- Issue in PA negotiations: emphasis of developing countries on better distribution of manufacturing capacities requiring transfer of technology, IPR management, funding, workforce and market access
- Art. 11 PA: controversy over "VMAT" or more prescriptive approach.
- Watered down language on IPR avoiding competence challenge. Authorizing language, national measures and respect for international obligations.
- Search for compromise language: BBNJ Part V as possible blueprint
- Limits of public authority vis-à-vis corporate prerogatives. Negative experiences with WTO waiver attempt and implementation of Art. 66.2 TRIPS
- Importance of practical initiatives supporting PA, eg. WHO's hubs and public-private partnerships

HUMAN RIGHTS LAW

- Human rights major casualty of COVID-19, both civil/political and social/economic
- Growing practice on limitations and derogations to human rights. COVID-19 as first health emergency. Derogation mechanism (Art. 4 ICCPR, Art. 15 ECHR). Limited compliance with notification obligations. Engagement of human rights institutions and mechanism, national and international litigation
- Civil society push for overt human rights provisions in PA, but only principle left (Art. 3). Contra:
- 1) PA not human rights treaty, WHO not a human rights organization, limits of the epistemic community
- 2) Risk of adding extra layers of political controversy and complexity
- 3) Risk of relations with HR treaties and prompting retrogressive measures as PA later and lex specialis
- 4) Reliance on HR ecosystem. Importance of avoiding incompatible provisions.

SOME BROADER CONSIDERATIONS

- Peculiarities and challenges of the PA:
- 1) Broad and ambitious scope, from deep prevention to health products allocation
- 2) Narrow object: pandemics
- 3) Contrast with IHR with limited scope but broader object
- 4) Prevention and preparedness require systemic measures – prevention paradox and political priorities
- Second thoughts on rationale and appropriateness of treaty and negotiating process

SUCCESS OR FAILURE?

- Uncertainty on final outcome – emphasis on deep north-south cleavage and mistrust
- Disaggregation of political groupings: what are "global north and global south"?
- Achievements of draft, moving beyond the status quo:
- 1) First international regulation of upstream and integrated prevention and surveillance
- 2) Validation of One Health in an international treaty
- 3) First international obligations on pharmaceutical R&D
- 4) PABS as potential protected normative space for public health cooperation
- 5) Strengthening hard core of global health law
- Can the treaty fail? How? What will happen in case of failure?