



The clinical foreground and industrial background: Customizing national strategy for COVID-19 testing

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Abstract

The WHO's exhortation to countries to "Test, Test, Test," in the light of the COVID-19 pandemic has led to an unprecedented global effort to increase testing capacity for SARS-CoV-2 infection. However, there exists a notable absence of debate about national industrial customization of this testing capacity. The paper contributes a conceptual integration of economics with public health to illustrate the vital industrial organization of health systems. The paper comprises an analysis using a five-layered approach to the industrial complexity involved with building technological capabilities and policy instruments to accelerate Covid-19 testing. A unique combination of systems literature gaps in economics and public health, intelligence gleaned from active pandemic policy-public health action networks, and crossnational analyses of industrial capabilities in firms using a qualitative heuristic along with a review of observational testing data. The focus on accelerated testing points to unspecified assumptions and specific assumptions of technological capabilities. The results show that there are idiosyncracies in local production capabilities (supplier versus non-suppliers) and export abilities that are mixed between and within Low Middle Income Countries (LMICs) and Higher Income Countries (HIC) countries, which makes them less easy to differentiate solely by their industrialized status. Early analysis provides confirmation of the importance and localized devolution and policy contexts for industrial supply chains. The disproportionate focus on diagnostic kits production as opposed to potential economic development interventions has missed important opportunities thus far. The next steps for extending this research include evaluating how those in different national industrial supplier categories adapt to global markets, constraints, and demand-side uncertainties.

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1. Introduction

The WHO's exhortation to <u>"Test, Test,"</u> has led to an unprecedented global effort to increase testing capacity for SARS–CoV-2 infection. Notably however, a debate about national customization of the industrial context to enable the roll-out of testing is missing. Furthermore, countries often display idiosyncratic priorities, difficult industrial policy choices and organizational features. Their Covid-19 testing strategies will therefore be unique. Without this foundational industrial context in which firms - public or private - must invest in technological capabilities, even if to import, manage, or deliver testing, the WHO advisory risks a formidable coordination challenge between global health goals and domestic realities for present and future pandemic response.

The WHO can play a significant role in ensuring that national industrial strategies are not constrained by donor biases and preferences, and generate open debate about the conceptual models and evaluation frameworks for emergency global health. When development agencies or the media focus disproportionately on the testing regimens and strategies of South Korea, Singapore, New Zealand, and Iceland, they select with bias one type of triad use (high income industrial suppliers of very different types, or worse, equating high income countries with those with supplier capabilities).

What determines a country's COVID-19 testing capacity? We posit two hypotheses. Firstly, we hypothesize that that only industrial supplier countries can implement the WHO's testing strategy. Others will import or not test. Secondly, from a clinical and public health point of view, both the individual tests and the testing strategy chosen depend on the ability of the test to inform decision-making in a meaningful, timely, and scalable manner. Towards this, we find that at least 7 specific types of clinical foreground-industrial background uncertainties link economics to health and fundamentally determine any country's ability to test by establishing fundamental feedback challenges that must occur between health and economics.

The WHO would do better to seek an appropriate benchmark by type of technological capability or industrial goals of the co-evolving health system e.g. two countries that decide to rely on imports but successfully flatten the curve versus those that decide to produce from scratch or ramp up production; similarly countries that have low test kits, testing, but high use of remdesivir or other perceived complements. Finally, 'developing' countries with industrial capabilities that locked down and used the time to build industrial bases versus those who did not.

A further premise of the paper is that health services planning, implementation, and research require a fundamental shift to a systems analysis and one that is informed by an evolutionary, institutional economics approach.^{2 3 4} A clinical and biological imperative is built on a much neglected economics foundation of innovation and industry dynamics.⁴ Past research has found that outcome-driven capacity building requires local production capabilities, and may be a critical social determinant of health in meeting domestic and global health goals.^{4 5} COVID-19 health evaluation must consider the evolutionary, institutional features of technological search and learning required of firms to create diagnostics or build lab and therapy or vaccines supply chains, in fast-moving field contexts.⁶

The objectives are thus to clarify: 1) overlaps between COVID-19 testing realities, economics of innovation and industry and public health analysis; 2) Illustrate a brief country case taxonomy for future research where the economics elements are discussed further.

2. Methods

In the spirit of capturing more systemic and evolving features, the paper combines five (5) methods to track industrial complexity:

- (1) Extensive secondary literature review specifically of the combined economics-public health Covid-2019 literature.
- (2) Dynamic information from COVID-19 professional clinical, public health, economics, and public policy networks, supplementing (1) with the verification from professional, policy or advisory networks where two of the authors participate. Specifically, direct participatory membership of a unique 150+ member organization Covid Action Collaborative⁷ in India including COVID-19 clinical management, testing roll-out with government approved kits and partners, and testing and relief logistics. The paper also sourced information from wider professional ties to/memberships in multidisciplinary health systems research and engagement: think-tanks, grassroots, academic, clinical/medical practice, governmental economics, primary health care and public health networks.
- (3) Active monitoring of other economic-health domains The team used a wide lens on missing layers of industrial complexity in health system analysis. By monitoring data and trends from active state-level engagements, diagnostic testing contexts on the ground, and by tracking priorities of policy facing public health groups, the team was able to develop hypotheses and compare and contrast across regions, field-data, and disease types, to ensure the approach was robust.

- (4) Review of primary and secondary observational data from Indian organizations involved in testing The team involved expertise directly involved with and able to assess glean observational data on practical testing hurdles such as stocking and procurement faced by public and private sector organizations including primary health centres (PHCs). Several healthcare-seeking and protocol changes were discussed extensively in real-time: Changes in health-seeking behaviour in response to point of care diagnostic kits or other roll-out strategies, priorities for obtaining specific diagnostic kits, varying policy or private sector endorsements of experimental therapies such as antiretrovirals or hydroxychloroquine, rapidly growing vaccine efforts, and yardsticks such as ventilator purchase estimates that are more reflective of ground-level changes focused on COVID-19.
- (5) Cross-national analyses using a heuristic Finally, the team sorted countries into successive layers of industrial complexity by applying an evolutionary, institutional 'triad'. Heuristics are thought experiments, rules of thumb, short-hands, in a range of disciplines, used to analytically differentiate cases or build taxonomies. They offer several advantages in fast-changing contexts. The 'triad' here was developed in a context of detailed health industry analysis, and is a qualitative heuristic comprising: a) Production which refers to the presence of a domestic pharmaceutical, drugs or devices industry; b) Delivery which analyses the components of the existing health care system; and c) Consumption which examines the demand features and shaped by single or collective access, such as health insurance coverage. The triad heuristic prompts scrutiny of industrial assumptions of how healthcare functions.

3. Results

Using the 5 layers of analysis, the paper finds that COVID-19 testing has critical economic dimensions of technology and industry with high uncertainty, which potentially affects how the clinical phases are viewed and which types of technology or industrial partnerships are promoted. By using the layered methods, the paper approaches health policy and epidemiological data with a technological learning perspective, used in economic development. The intertwined economic-health features must be addressed alongside with the following scenarios: a) Screening during asymptomatic/pre-symptomatic phase; b) Diagnosis of symptomatic disease; c) Determination of viral shedding in the convalescence phase for decision-making on de-isolation; d) Epidemiologic surveillance.⁸

The paper thus finds it necessary to specify distinct clinical foreground-industrial background uncertainties as follows in order to integrate economics with public health. This differentiation of the interface between public health and economics therefore can be sectioned into

uncertainty sources and their effects. A test result is critical because of the clinical decision that it informs. Thus, test performance must be ascertained in multiple use cases and its uncertainties minimized.⁹ However, clinical indecision draws from and compounds these uncertainties leading to marked challenges of industrial supply and demand, and the logistical bottlenecks of viable delivery.

One result is thus there are at least 7 specific types of clinical foreground-industrial background uncertainties that link economics to health:

- 1. In any public health emergency, clinicians struggle to separate real medical signals from noise, where professionals co-evaluate multiple criteria when considering testing: the impact on subsequent decision-making; the availability, ease of administration, and extent of test reliability; the choice of which test to administer; prioritization of whom to test; comparability across populations and viral strains; the potential to effectively and equitably make the test available.
- 2. National COVID-19 testing cannot be independent of testing for other co-circulating pathogens such as H1N1 influenza, dengue etc. The detection of one viral infection does not rule out other pathogens as co-infection is possible, posing a diagnostic challenge for science, engineering, business and the economic models of national use.
- The national scale of testing varies. In the context of asymptomatic transmission, testing is difficult, if not impossible, to administer effectively due to questions on whom to test, cost constraints, lack of trained technicians, or logistical challenges in transportation of tests.
- 4. Technology, industrial scale, and investment uncertainties persist. Attributes that determine scalability of testing technologies significantly impact the fiscal incentives and industrial role of diverse stakeholders. Intrinsic attributes of the test such as sensitivity and specificity confound interpretation and clinical decision-making thereby complicating testing rollout and strategy. ¹⁰ Clarity is emerging only now on which tests to use, factors such as the "window period" or the phase of infection where a person's test results may be negative despite established infection, effect of evolving variation in virus strains, ¹¹ quantum of viral shedding on test results, influence of sample collection technique, transportation temperature, duration, and the training level of laboratory technicians. The reliability of batching, acceptable throughput, and turnaround time of the tests are also uncertain.⁸

- 5. Stigma complicates testing, and the demand for kits and investments. Several countries have high stigma and low privacy associated with testing, making widespread testing difficult. On the other hand, an anxiety to verify the status of illness might prompt greater demand for tests that reduce availability for those who may need it most.
- 6. 'Single disease' health management and testing regimens do not reflect multiple health challenges. An emphasis on (emergency) COVID-19 at the cost of other (chronic) public health priorities and programs has arguably derailed HIV, TB and malaria treatment, supply chains of critical medicines, and medical supplies in several countries.
- 7. Health professionals and specialists respond to uncertainty differently. Epidemiologists, virologists and clinicians will differ from each other on defining the smallest margin of error and training to deal with uncertainties.¹²

These seven uncertainties fundamentally transform what a priori is known about any country's ability to test, and, in the absence of a WHO strategy that acknowledges the challenge of test kit availability worldwide, only compound the uncertainties. The 7 identified uncertainties undermine fundamental feedback that must occur between health and economics.

3.1 Applying a heuristic to industrial complexity

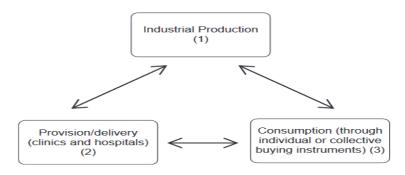
Therefore, the compounding of the two-way clinical foreground-industrial background uncertainties fundamentally transforms the basis of how countries strategize, engage in iterative learning, and respond. As the 7 uncertainties show, industry complexity is a crucial missing element of the social determinants of a health system.^{2 4 5} The complexity of health systems can therefore be translated in two ways: first, complexity exists because public health and industry are intertwined in a system whose contours and boundaries are ever changing. Second, industrial complexity itself is an integral part of the economics of health systems.

The WHO recognizes but does not offer a framework to interpret the high degree of industrial and technological learning uncertainties or regulatory hurdles.¹³ It does not address how industrial assumptions of health policy delivery can be made explicit or whether they are necessary.

The last layer is to assess how systems may be represented and how they change, using the following evolutionary-institutional (EI) heuristic: this 'triad' offers a qualitative insight-generating mechanism to track both economic considerations and health priorities.⁴ ¹⁴ The heuristic can be applied at the level of individual firms, industries and countries to reveal health systems challenges.

Three co-evolving institutional domains of production, demand and delivery are represented below.

Fig 1: The Institutional Triad



Source: Srinivas (2012), Market Menagerie, p. 8

Countries with similar assumed development or industrial features may exhibit different interactions between the three evolutionary domains of the triad of Table 1. One representation is shown below where the activity at the level of organizations is indicated.

Table 1: Policy Domains and Economic Activities of the Institutional Triad

Institutional Vertex	Policy Domain	Characteristic Economic Activities
1	Production (Industrial Policy, also Innovation, Science, R&D)	Manufacturing, R&D, prototyping, supply driven 'catch-up' in medicines (generics and other), vaccines, diagnostics and devices.
2	Provision/ Delivery (Health Policy, and some infrastructure and Industry policies)	, , , , , , , , , , , , , , , , , , , ,
3	Consumption (Health policy, especially Insurance policies)	Individual or Collective buying instruments: Pay as you go, out of pocket cash payments, collective insurance - formal and informal.

Source: Srinivas (2020)¹⁵ (adapted from Srinivas, 2012).

Using the heuristic, three elements of COVID-19 testing response in countries are analyzed. Table 2 displays a focus on production capabilities: (i) the extent of testing undertaken; (ii) whether the government and healthcare industry adopted an import or export driven strategy and (iii) the degree of local manufacturing. Rather than split the world into 'developed/developing', or by high or low income alone, countries are contrasted by industrial capabilities in order to understand better their ability to develop COVID-19 test kits and their subsequent roll-out. The emphasis is on democracies to understand the full range of

institutional variety. China is included here only because it was where the COVID-19 pandemic was first tracked, and yet so little is understood of its response. Vietnam is included because it had amongst the lowest, rapidly checked spread. Neither represents all potential degrees of freedom represented by the heuristic for COVID-19, although the heuristic can be applied to non-democracies or those with little or no private health industry e.g. Cuba.

The variability of the three domains of the triad (1,2,3) is shown below. In a pandemic, previously non-producer countries, even those with relatively strong delivery (2) and consumption capabilities (3), will have to rely heavily on foreign producers or emerging domestic firms, regardless of industrialized status. The table also outlines a country's strategy with regard to testing, export or import reliance (of pandemic-related equipment, kits, PPEs, swabs etc.) and manufacturing capabilities within the context of the COVID-19 pandemic. The heuristic is a means to develop further hypotheses and methodologies rather than merely categorization of data. As the table indicates, the taxonomy of countries by region or by assumed capability is counter-intuitive in many cases, as the heuristic shows: many lower-income countries have shown some local self-reliance. Furthermore, as more data was analyzed as the pandemic unfolded, it became evident that the traditional category of 1 ("production"), required further differentiated to emphasize ongoing technological learning and production investments of different grades and quality.

Asterisks were then appended: The category (1) then became the baseline status of a producer, while (1*) represented successful national response to local context but may still require imports, and (1**) is almost fully self-reliant. More importantly, and intuitive to evolutionary economists, there was considerable variety in how this was achieved, but insufficient detail yet available about which organizations (.e.g military, public hospitals, national labs, private firms, consortia etc.). Thus, the full use of the heuristic toward analysis of institutional and organizational variety was not explored. The nature of the variety and how this is then interpreted is critical to health systems improvements. It is also pivotal to inference and judgement in economics and the role of technological capabilities and why they are considered important or in what ways they aid a nation's development (Srinivas 2020), This point deserves emphasis because while health systems research may benefit from industrial organization analysis, the methodologies to evaluate such background rather than focusing on the phenomena of technological learning, still relies disproportionately on traditional income per capita classification of country aid, trade, and development analysis.

Table 2: COVID-19 industrial response from countries (by region)

Country	Testing strategy	Triad domains
N.A	African countries	(4.0)
Morocco	incremental testing; primarily import driven; limited local manufacturing	(1,2)
Egypt	limited testing; primarily import driven; incremental local manufacturing	(1,2)
Senegal	high testing; importer; incremental local manufacturing	(1*,2)
Ghana	high testing; importer; incremental local manufacturing	(1,2,3)
Tanzania	low testing; import driven; limited local manufacturing	(2)
Kenya	incremental testing; importer; extensive local manufacturing	(1*,2,3)
Nigeria	incremental testing; importer; extensive local manufacturing	(1*,2,3)
South Africa	high testing; import driven; limited local manufacturing	(1,2)
	High-income countries	
USA	extensive testing; primarily import driven; incremental local manufacturing	(1,2,3)
UK	delayed testing; primarily import driven; limited local manufacturing	(1*,2,3)
Germany	high testing; exporter; extensive local manufacturing	(1*,2,3)
	Asian countries	
Israel	delayed & limited testing; extensive R&D and local manufacturing	(1**,2,3)
India	extensive testing; increasing export intensity; rapid shift to local manufacturing	(1**,2,3)
South Korea	extensive testing; export intensive; extensive local manufacturing	(1**,2,3)
Vietnam	extensive testing; export intensive; extensive local manufacturing	(1**,2, 3)
China	extensive testing; export intensive; extensive local manufacturing	(1**,2,3)
Singapore	delayed testing; importer; incremental local manufacturing	(1*,2,3)
Japan	limited testing; import intensive; limited local manufacturing	(1,2,3)
Sri Lanka	high testing; importer; incremental local manufacturing	(1,2,3)
Bangladesh	decelerated and limited testing; importer; no local manufacturing	(1,2,3)

Pakistan	decelerated	testing;	importer;	(2,3)
	limited local manufacturing		ırina	

[Source: triad from Srinivas (2012,8). Compiled by the authors from global news coverage, as well as ministry, country and WHO reports over the lifetime of the pandemic (March 2020 - present). In the context of COVID-19, production (1) refers to the presence of domestic manufacturing, particularly of COVID-testing kits (except in the cases of Egypt, Sri Lanka and Pakistan, where local kits have not been developed at the time of writing to the best of the authors' knowledge. However, other pandemic-related manufacturing capabilities exist); (1*) has successfully responded to local context but may still need some imports; (1**) is almost fully self-reliant; delivery (2) analyses essential outreach of clinics and hospitals (3) is individual or collective consumption: covered by out-of-pocket payments, insurance or other system of payment coverage for easier access). NB: The authors have attempted to include as many groups as are relevant in democracies since the interest lies in exploring the various institutions and their interactions that determine health care availability and efficacy.]

Table 2 shows that using a heuristic can generate additional patterns and hypotheses, contested sub-categories of the nature of prototyping or manufacturing, and appears to indicate that there is no linear pattern to the traditional categorization of countries by industrialization or per capita income in responding to the local production of COVID-19 testing kits. Rather, the 7 uncertainties that link industry and health force rapid national adjustment of existing technological capabilities in unexpected ways. The following contexts are identified as of particular interest.

3.2.1 Trade-offs depending on economic structure and density

Testing decisions are part of a complex system of industrial decision-making for production (1), which depends in turn on the demand and delivery bottlenecks of each country. Isolation measures are hard to enforce in densely populated countries and halting economic activity deepens systemic inequality. Yet, the volume of tests required and the lack of local production capabilities make extensive testing unfeasible. Senegal's low population density may differentiate it from Ghana or South Africa, but its industrial production decisions (1) are also shaped by existing health systems capacity (2,3). Disparate countries such as Ghana, Israel, and China have tried pooled testing in the face of industrial supply shortages - combining biological samples from multiple subjects that are tested together to reduce burden (1,3). Potential reductions in the sensitivity of the test are balanced against conserving limited resources such as diagnostic kits, laboratory capacity and medical personnel. Non-democracies may respond in unique ways because 1,2, and 3 are tightly linked and in some, there may be little or no private industry.

Beyond ramping up testing kits production and testing (1,2), Ghana simultaneously escalated contact tracing efforts (which hones 2,3). Several South Asian and African countries have large low-income and daily-wage informal workers, rendering 'work from home' mandates, with extended lockdowns economically disastrous. In such cases, local production ramp-up and technological innovation may be preferred to rapidly open up the economy. Thus,

technological capabilities may be an effective way to address inequalities and keeping more policy options available.

3.2.2 Technological focus (complementary measures to testing)

As the triad demonstrates, the supply 'chain' is far from deterministic or linear but acts as a co-evolving, iterative demand-supply network with open-ended outcomes, switching, and continuous search and learning. Imports and local production may be judiciously mixed: Singapore imports swabs, but invests in other more profitable, reliable, or locally relevant produced innovations. Nigeria and Ghana tap into larger supply chains of firms in food logistics to procure the tests and equipment they needed to cope. Despite Japan and the UK having sizable diagnostic and industrial capabilities, Japan focused on contact tracing and surveillance methods, and both delayed the production of kits and testing capacity.

Kenyan manufacturers in consumer goods and breweries for instance switched to sanitizer production and firms built up the production of swabs, masks, oxygen supply kits, 3-D printed face shields, and viral transport medium.¹⁷ Nigeria was able to harness local innovativeness as genomics companies manufactured "mobile" laboratories and blood & oxygen supplier firms built drive-through testing facilities (1) (2).

Innovation is plenty: Ghana is developing antibody tests, has used drones to transport coronavirus tests and has locally produced a 1-hour assembly ventilator. Singapore's electric supercar manufacturers built ventilators, and stationery manufacturers created a robot intended to assist medical personnel and transport medical essentials.

3.2.3 Industrial capabilities and wider adaptability and governance experience

Even with existing technological capabilities, governance is essential. South Korea and Vietnam coordinated public cooperation, and extensive contact tracing and isolation protocols. Cold-war nation-building and tropical and infectious diseases preparedness is substantial, especially in Vietnam from its communist era.

Senegal's preparedness history included enacting mock outbreaks, with emergency epidemic planning. They also collaborated with the UK to develop cost-effective tests¹⁸ which yield results in minutes.

3.2.4 Pivots to suit and support local needs

The national customization context will require a domestic industrial response especially in the context of import constraints but has to rapidly embed it in local context. Having the technological capabilities to produce kits (1) is insufficient unless they are delivered (2) to use in testing, or match customized demand (e.g. to schools, older populations, speed requirements etc) but also the consumption context (3): out of pocket, free, insurance cover etc.

The UK and Singapore both performed a late pivot in testing strategy, but despite the UK's excellent scientific labs, Singapore more tightly structured health delivery (2) to dictate production priorities (1) and use governmental control and private partnerships to manage all three domains (1,2,3).¹⁹

With immense (2,3) challenges, India has introduced COVID-19 public insurance coverage or price controls (3), required private insurers to offer COVID-19 cover, and accelerated COVID-19 specific R&D and local manufacturing. It is among the fastest growing and largest exporters of test kits and PPEs, while keeping deaths/100,000 low. Industrial self-reliance (Atma Nirbhar)²⁰ is the new policy motto.

Israel's initial tech-driven contact tracing managed the shortage of imported chemical reagents and equipment. With increased R&D and local manufacturing of test kits²¹ (including reagents), they were able to scale testing and focus on overseas customers (including India).

Meanwhile, Bangladesh and Pakistan decelerated testing rates gradually for diverse domestic reasons on both health and industrial fronts.

3.2.5 COVID-19 test kit exports

Perhaps most notably, some countries have rapidly become exporters of COVID-19 kits, for reasons ranging from existing technological strategies, developing updated import-substitution strategies, and seeking profit opportunities. South Korea and China were two of the earliest countries to ramp up exports. Vietnam began as early importer, but quickly became an exporter; India has had a rapid scale-up on PPEs, an essential segment for COVID-19 testing and may now be the world's largest democratic health manufacturing industry for testing kits and PPEs. The US was initially unable to use industrial policy to resolve supply chain bottlenecks, importing components, chemicals, reagents, and other essentials required to locally produce testing kits. It has also faced challenges on state-level procurement bids for PPEs and testing kits.

China and India made different choices on testing kits and local production shaped by specific geopolitical considerations, trade restrictions, new approval processes, and make-at-home regulatory hurdles. China's export restrictions also resulted in medical goods such as face masks, tests kits and protective equipment intended for the US, being stranded. Geopolitical tensions have also arisen between China and India, and Indian pharma companies had requested an airlift of key (Active Pharmaceutical Ingredients (APIs) from China,²² tests procured were reported as faulty and returned,²³ but now trade is considerably restricted in

the latter part of 2020. The US and Brazil have asked India for hydroxychloroquine supplies. Consequently, rather than view countries by per capita income, industrial governance and import-substitution geopolitics may display stronger explanatory power and can be tested further at the level of firms and regulation.

3.2.6 Turnaround time

The most recent industrial challenge is producing rapid test results. The turnaround time, a metric of the robustness of the industrial process including availability of human resources, automation capability, types of testing kits available, lab supply chains, and inherent characteristics of a test (that balance efficiency and accuracy), is a critical factor in guaranteeing testing success through quicker tracing, isolation, and quarantine. Longer turnaround times in high population densities²⁴ put additional strain on overwhelmed health systems. Uncertainties and delays can compound the economic dilemmas and fiscal and health imperatives. Industrial complexity shows that experimenting with vertically integrated or rapid just-in-time production systems for testing are visible across countries. US delays on test results in Table 3 prompts new questions for the assumed relationships and hierarchy of expertise of prototyping, manufacturing, or service firms, science, clinical translation, and emergency public policies.

Table 3: Estimated testing turnaround times (averages and estimates in days and hours)

Country	State	Data as of	Average estimates
US		30-Jul	4.27 days
	Missouri	22-Jul	7 days
	Kentucky	11-Jul	3-5 days
	Cleveland (hospital patients/critically ill)	11-Jul	24 hrs
UK		9-Jul	24-48 hrs
India			
	Tamilnadu	22-Jul	7 days
	Telangana	9-Jul	4-5 days
	Karnataka	9-Jul	3 days
	Kerala	22-Jul	2-3 days

	Rajasthan	26-Apr	4-5 days
	Madhya Pradesh	26-Apr	6 days
	West Bengal	26-Apr	3-4 days
South Africa		6-Jun	12 days

Source: Compiled by the authors from various news sources.

4. Discussion

The WHO's one-size-fits-all exhortation to 'Test, Test, Test' is missing large elements of national industrial foundations and system complexity attributes, potentially compromising public health effectiveness. An evolutionary- institutional (EI) approach to complexity, particularly in contexts of uncertainty, technology transfer, embedding and customization challenges, is highly relevant to technological learning bottlenecks and testing specifics. 4,14 While the paper has focused on the co-evolution of production capabilities of testing kits by 'grade' 1, 1*, 1**, a similar exercise could be undertaken for differentiating between different capabilities for (2) and (3)with clinics, hospitals (2) and insurance or other systems of access (3). For instance, countries such as Sri Lanka and the UK have free and universal care while Bangladesh and Pakistan, who typically do not have strong (3), have introduced free testing to improve access to health care. In India and South Korea, COVID-19 specific insurance has also been provided alongside free testing. Therefore, national customization strategies are essential.

Furthermore, ignoring the industrial foundations of health systems, and not clarifying the conceptual tools and methods to contrast countries, results in faulty comparison and evaluation by case count or mortality rates, when in fact more relevant and measurable industrial and technology policy criteria exist. Focusing on epidemiological or clinical data alone disregards seemingly mundane but potentially dynamic business and industrial considerations such as equipment production and sourcing, building reliable supply chains, rapid just-in-time production of tests and test results, embedding repair, sanitizing, and replacement of equipment as an essential element of functioning industrial systems. A too-easy imagined jump from lab to clinical translation short-circuits these essential elements. The economic development priorities and attention to self-reliance in many of these elements, defines national autonomy and local production capabilities, which influence COVID-19 response.

Each policy decision has important make-versus-buy considerations and problem-solving challenges. What the WHO leaves unsaid is that countries whose firms have high production (1) capabilities will still require decisions of export restrictions, incentives to their new or old

diagnostics firms, and regulatory design pressures to ensure the appropriate efficacy is reached. In order to manufacture, indigenously source or import diagnostic kits, the institutional domain (1) requires policy attention, clarity of future agenda, strategic resource allocation, and industrial reorganization in a short time frame.

'Testing for all' translates to industrial just-in-time availability and delivery or other production capabilities, demand-side buying systems, and delivery logistics and partnerships. The skew in global availability and response is nationally determined. Global Active Pharmaceutical Ingredients (APIs), vaccines, diagnostics, reagents, or instrumentation panels are dominated by some global firms, original equipment manufacturers or by some countries. Thus, even beyond COVID-19 test kits, is the fundamental industrial basis of COVID-19 response as a whole.

The qualitative heuristic also offers dynamic insights on complementary and substitution approaches for testing of COVID-19 in the context of other therapies and diseases, not as a standalone strategy. For instance, the increased use by some of hydroxychloroquine in COVID-19 treatment generates a new triad of analysis for lupus or malaria, resulting from stockpiling and diverting of resources to those diseases (e.g., US' remdesivir²⁵ and also anticipatory strategies for COVID-19 vaccines). Because the triad's domains co-evolve, there is no a priori 'best' testing strategy without the national industrial policy and governance context.

5. Conclusion

While the WHO acknowledges a pandemic-related shortage of equipment due to supply chain disruptions²⁶, more customization is essential. As the paper shows, even countries that have some technological capabilities adopt different national customization paths, and the industrial complexity of their response is dictated by at least 7 types of economic-health uncertainties. Industrial policy is evidently an essential determinant of health and a more systemic response is needed. The WHO may do well to constitute expert groups and convening on policy instruments such as procurement or other advance market commitments for industrial manufacture and market variety. In epidemics and pandemics, testing kits or other health technologies can thus become available to all countries in the manner of COVID-19 vaccines efforts by GAVI and others. The evidence thus far demonstrates that clinical foreground responsiveness is inextricably linked with industrial background considerations.

Reference

- 1. The World Health Organization: WHO Director-General's opening remarks at the media briefing on COVID-19 11 March 2020 https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-COVID-19---11-march-2020 (accessed 16 April, 2020).
- 2. Greenhalgh T., Papoutsi C. (2018) Studying complexity in health services research: desperately seeking an overdue paradigm shift. *BMC Med* 16, 95 https://doi.org/10.1186/s12916-018-1089-4.
- 3. Shiell A, Hawe P, Gold L. (2008) Complex interventions or complex systems? Implications for health economic evaluation. BMJ;336(7656):1281–3.
- 4. Srinivas S. (2012) Market Menagerie: Health and Development in Late Industrial States, Stanford University Press.
- 5. Mackintosh, M, Banda, G, Tibandebage, P, Wamae, W. (eds.) (2016) Making Medicines in Africa: The Political Economy of Industrializing for Local Health. London: Palgrave Macmillan. Open access http://www.palgrave.com/us/book/9781137546463.
- 6. Rao, P and Srinivas, S (2020) Economics and Public Health: a case for interdisciplinary cohesion in the time of Coronavirus. https://www.innogen.ac.uk/sites/default/files/2020-04/The%20need%20for%20economics%20involvement%20in%20public%20health%20-%20Lessons%20from%20the%20Coronavirus.pdf (accessed 13 August 2020).
- 7. Covid Action Collab. The number of organizations and impact is now larger https://covidactioncollab.in/.
- 8. Cheng MP, Papenburg J, Desjardins M, et al (2020)
 Diagnostic Testing for Severe Acute Respiratory Syndrome–Related Coronavirus-2: A
 Narrative Review. Annals of Internal Medicine doi: https://doi.org/10.7326/M20-1301 [Epub ahead of print April 13, 2020].
- 9. FIND SARS-COV-2 Diagnostic Use Cases. www.finddx.org/COVID-19/dx-use-cases/ (accessed 16 April 2020).
- 10. Zhao J, Yuan Q, Wang H, Liu W, Liao X and Su Y et. al (2020). Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. Clinical Infectious Diseases, , ciaa344 https://doi.org/10.1093/cid/ciaa344 (accessed April 16, 2020).

- 11. Tang X, Wu C, Li X, Song Y, Yao X, Wu X, Duan Y et. al (2020). On the origin and continuing evolution of SARS-CoV-2 National Science Review, nwaa036 https://doi.org/10.1093/nsr/nwaa036.
- 12. Gelijns A C, Zivin J G, & Nelson R R (2001) Uncertainty and technological change in medicine. Journal of Health Politics, Policy and Law, 26(5), 913-924.
- 13. Advice on the use of point-of-care immunodiagnostic tests for COVID-19, Scientific Brief, World Health Organization. https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-COVID-19 (accessed 30 May 2020).
- 14. Srinivas, S. (2016). Healthy Industries and Unhealthy Populations: Lessons from Indian Problem-Solving. In Mackintosh et al. (Eds.) Making medicines in Africa (pp. 183-199). Palgrave Macmillan, London.
- 15. Srinivas, S. (2020). A new economics for health, in Mehdi, A. and I. Rajan (eds) Health of the Nation (Oxford: Oxford University Press).
- 16. Cash R, Patel V (2020). Has COVID-19 subverted global health? The Lancet, Volume 395, Issue 10238, p. 1687-1688, ISSN 0140-6736, https://doi.org/10.1016/S0140-6736(20)31089-8.
- 17. Local manufacturing for health care has become high politics during the COVID-19 Pandemic https://www.open.ac.uk/researchprojects/innovation-cancer-care-africa/news/local-manufacturing-health-care-has-become-high-politics-during-covid-19-pandemic (accessed 30 July 2020).
- 18. A Senegalese innovation lab is helping the UK develop a 10-minute coronavirus test kit https://qz.com/africa/1816621/coronavirus-rapid-test-kits-to-be-made-in-senegal-with-uk-help/ (accessed 13 August 2020).
- 19. Faced with a spiraling coronavirus testing scandal, the U.K. pledges to build a diagnostics industry https://fortune.com/2020/04/02/coronavirus-testing-nhs-uk-healthcare-workers/ (accessed 30 May 2020).
- 20. Building *Atmanirbhar Bharat* and overcoming COVID-19. https://www.india.gov.in/spotlight/building-atmanirbhar-bharat-overcoming-covid-19. (accessed 13 August 2020).

- 21. Israeli firm developing 30-second coronavirus breath test. https://www.livemint.com/news/world/israeli-firm-developing-30-second-coronavirus-breath-test-11595557770201.html (accessed 13 August 2020).
- 22. Indian pharma companies want government to airlift APIs from China. https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/drug-coswant-govt-to-airlift-apis-from-china/articleshow/74956938.cms?from=mdr (accessed 30 May 2020).
- 23. Centre decides to withdraw faulty Covid 19 antibody test kits, cancels import orders from China

https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/centre-decides-to-withdraw-faulty-COVID-19-antibody-test-kits-cancels-import-orders-from-china/articleshow/75406955.cms?from=mdr (accessed 30 May 2020).

- 24. A Cheap, Simple Way to Control the Coronavirus https://www.nytimes.com/2020/07/03/opinion/coronavirus-tests.html (accessed 28 July 2020).
- 25. US secures world stock of key Covid-19 drug remdesivir. https://www.theguardian.com/us-news/2020/jun/30/us-buys-up-world-stock-of-key-covid-19-drug (accessed 03 July 2020).
- 26. Shortage of personal protective equipment endangering health workers worldwide https://www.who.int/news-room/detail/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide (accessed 21 August 2020).
- 27. Srinivas, S. (2020) Institutional variety and the future of economics. The Review of Evolutionary Political Economy 1, 13–35. https://doi.org/10.1007/s43253-020-00010-7.