

A Novel Business Model to withstand the nCoV-19 Dual: Methodology for Using Universal Rapid Immunologic Test as an Identity Tag for Rapid Unpacking the Units of Population under Lockdown to Minimize Socioeconomic Shock of Pandemics

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ABSTRACT

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1 INTRODUCTION

Novel Coronavirus-19 has seriously hit multiple constituencies of life, livelihood and lifestyle. Emerging from an unidentified source in Wuhan, China, the virus currently has spread to every nook and corner of the world. China and some other countries seem to have handled the pandemic smartly and successfully cutting down transmission and restoring life. However, there are doubts if the success remains sustainable in the perspective of global mobility. But elsewhere in Europe, USA, Brazil, Russia and India the transmission seems to continue in an alarming proportion. Many other countries in Asia and Africa including Bangladesh show awful trends that threaten to destroy the economy in addition to claiming a heavy toll of life.

The entire world rich and poor is perplexed by the pervasive domination of the infection as no drugs or therapy appear to be certainly effective and lockdown of the population at home with limited continuance of essential and livelihood activities outside the home with designated protective equipment looks to be the only solution to contain transmission and save lives. However, such adynamicity of normal human activities in the contemporary setting of civilization certainly threaten to smash the economy, the essential pipeline to the provisions of human supplies and livelihood.

The dual task of saving lives as well as restoring human functions including production and service that keeps life, livelihood and economy moving, is currently a horrendous one and has posed great stress to state and global thinkers, leaders and managers. Trying to save one of these, invariably strikes the other to wicked proportions. Currently, the world suffers from both Covid-19 and dilemmas.

The Real Maze:

While lockdown appears to be an effective healthcare measure to contain the infection, it has a catastrophic effect on the human functions, livelihood and economy. On the contrary, measures to vitalize the later produces serious consequences on health outcomes. The doors out of this maze are not so simple to find with the current understanding and extent of human knowledge. As no known model seems perfect, a best evidence-based strategic approach with a PDSA (Plan-Do-See-Act) learning curve trajectory for damage control only promises to mitigate the devastating threat.

The Work-plan and its Rationale:

This module describes a work-plan that has potential to show the way out. This work-plan presupposes on many of the standing and contemporary scientific evidences. These include the fact that in the absence of a readily available vaccine, a natural herd immunity at the cost of heavy loss of lives appears to be the current fate of the epidemic if lock-downs are not maintained. Lock down causes severe shock to other constituencies of life and human affairs. However,

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it also observes with great relief that a large majority of the infections either have no symptoms or have insignificant symptoms without clinical consequences. It takes into account that an antibody response to nCoV-19 infection, similar to that with any other viruses, occur within 2-4 weeks of infection (Figure-1).^{1, 2, 3} It also takes into account that in monkeys there is a protective antibody response.^{4,5}

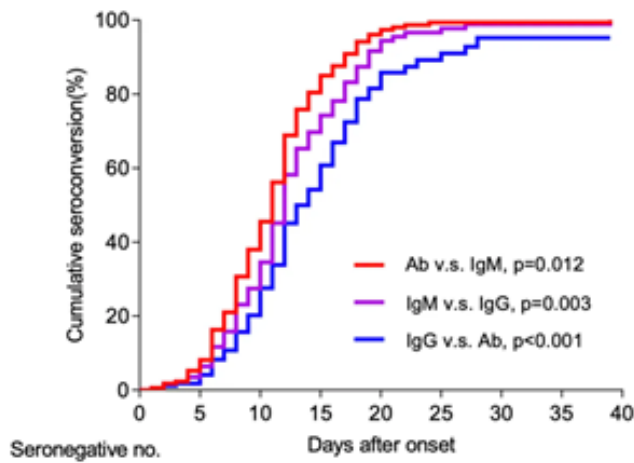


Figure 1. Showing Sero-conversion in Covid-19 with preliminary data

It also observes three broad patterns of the pandemic wave with respect to population affected and success of initial and continuing measures to contain the transmission (Figure-2). A rapidly developing high peak wave (**A type Curve**) as has been seen in Italy, Spain, USA, UK and Brazil in which a tall peak was attained within a short period of 2-3 months and plateaued for a time before showing decline. The length of the plateau measures the extent of high transmission phase. In this pattern, heavy pressure on the clinical side was observed with large number of deaths. The pressure on clinical load distracts healthcare systems from the public health measures, draws resources away from the later and makes integration and decision at leadership difficult. This pattern seems to display a **loose effective geographical control** of the pandemic. In this pattern withdrawal of lockdown threatens to prolong the plateau at its peak.

The second pattern was seen in many countries of Asia including China, Japan, South Korea, Vietnam and Hong Kong with a short and sharp peak generated within 2-3 months and falling off with a similar trend causing moderate demand on the clinical side, keeping death to a tolerable limit (**B Type Curve**). This pattern indicated success of the initial measures to slow down transmission and allows balanced attention to clinical and public health measures. This pattern of control can be viewed as a **timely effective geographical control** of the pandemic. This pattern allows quick withdrawal of lockdown but the results of geographical success are awaited to be seen in near future. There appears to be serious threats to its sustainability from essential human movements.

The third pattern is being observed in low and middle income countries like India, Pakistan, Malaysia and Bangladesh in which the peak is still unseen and the transmission is observed to be slowly mounting with yet low pressure to the clinical side (**C type Curve**). The plateau in this curve is feared to be longer. However, if the low-peak nature of the curve can be maintained through practicable and effective control measures, the total number of clinical cases at any point of time may well be limited within the management capacity of low-powered healthcare systems. This may cut down the proportion of the death due to care failure. As a consequence, the cumulative death figures of longer waves can also be kept low. This pattern is feared to create a broad wave lasting for many months without apparent signs of control. This pattern may be called **delayed effective geographical control** of the pandemic.

In this pattern the withdrawal of lockdown cannot be anticipated and prolongation appears inevitable. Essential prolongation of lockdown continues to have razing destruction on the economy, livelihood, psychology and other human affairs.

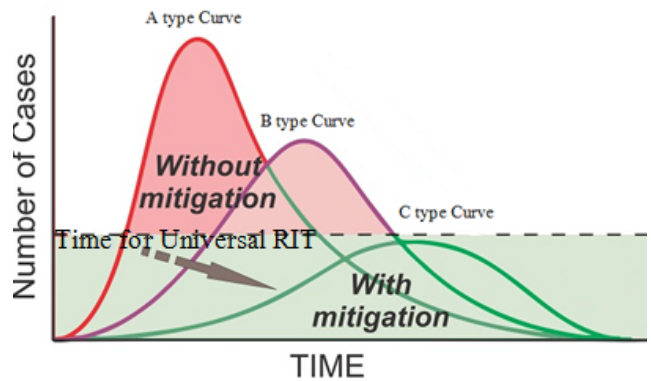


Figure 2. showing the Three Patterns of Epidemic Progression and Appropriate time for Application of Universal RIT (Arrow)

A fourth pattern may also emerge with a very low peak and a very broad base. The significance of the last could be in keeping the iron hot with a threat to other regions that may have achieved control. The US CDC warns long persistence of the virus in human habitation.² Therefore in-stead of arbitrary risk-prone steps, a theoretically founded, strong and sustainable strategy and methodology to lifting lockdown appears essential and vital.

An academically sound, technically feasible and administratively manageable measure, supported by available resources, to sustainably minimize the shock, is to be designed. *On the basis of established and contemporary scientific evidence it is likely that with over 3 months passing after the first case detection by now many persons of an affected community will have acquired silent infections and have recovered silently from it (as many as 80% may have silent infections).*^{7,8,9,10,11} These persons are to be considered at no great risk of further recent infection and are also

considered to be safe to the community in respect of spreading the infection. They can be deemed **immunologically safe** from nCoV-19 and at the same time **epidemiologically safe** to the community.¹² Therefore, they no longer require lockdown or isolation or quarantine. They may more assuredly and safely be set free to a **Lock-free Community (LFC)** to resume normal activities.

Along with such **immunologically and epidemiologically safe** persons a proportionate number of healthy persons, yet showing no evidence of infection that is **epidemiologically safe but not immunologically safe**, engaged in essential or vital human and economic activities, particularly if volunteering may be released under surveillance to the **Lock-free Community (LFC)** to fortify the vital workforce. Such mixing can be done with reasonable safety as is supported by the herd immunity concept in a 70:30 proportion. This substantially fortifies the workforce to re-fuel the production, service and economy.

The only requirement is to find a **reliable test** that can identify such persons with their immunologic and epidemiologic status with reasonable certainty and a **mechanism to handle the repopulation** of the workplaces under supervision and maintain surveillance on them. Detecting antibodies in the blood of such silently exposed or infected persons is a solution to identify such persons who are **sero-positive** (having developed detectable antibody response in their serum and deemed safe from further infections). The presence of antibody in the person's blood would certify their relative safety from the infection (**immunological competence**). **Concomitant detection of the viral antigens** in the same person's secretions would provide information regarding the community's safety from them (**epidemiological competence**) to release free and safe in the community.

Identifying the Instrument:

The currently devised Rapid Immunologic Test (RIT) Kit by Gonoshasthaya-RNA Biotech Limited, a sister concern of Gonoshasthaya like many such equivalent kits developed in USA and UK with sensitivity and specificity over 90% is expected to fulfill the requirement of the instrument.^{13,14} Unlike the sole antibody detecting kits developed elsewhere, this Gonoshasthaya Rapid Dot Blot kit is unique that it also includes a panel that detects the viral antigen.¹⁵ This makes the test kit extremely versatile in that if simultaneously applied the dual-acting kit can identify both the presence of antigen of the virus and the antibodies against it. It therefore ascertains both the safety of a person to the community and his own safety from the infection.

These kinds of tests therefore are able to identify Persons in respect of their Epidemiological (Safety for the Community) and Immunological (Safety of the Person) Competence. When such epidemiologically competent and immunologically competent persons in the locked down community can be identified, they can be suitably handled to repopulate the workforce **with greater confidence of containing the infection than is currently being done in an arbitrary manner** with high risk of the infection rate soaring

unmanageably high. The Test is also unique in that it requires **low level technology, minimal facility and performer training**; is **onsite and rapid in performance** necessitating a finger prick; is **instantly quick** in providing results; can be **performed semi-domestically**; is **highly Cost-effective** each test costing about 250-500 taka equivalent to US\$ 3-5 or less and is extremely **suitable for mass utilization**.^{15,16,17,18,19,20} Several such tests are also commercially available.

Current Concern:

It is being observed with concern that the contemporary state managements all over the world, heavily stressed with uncertainties of the suspension of the economic and livelihood activities, are attempting to arbitrarily open up normal life-related activities to observe the consequences and manage them with a full strength capacity available to them. This is not only risky for causing unexpected rise in the numbers of infections but also warns that if the clinical disease mounts to high numbers the current capacity and scope of healthcare facilities in many countries will seriously fail to provide essentials support to care and save lives. The number of available hospital isolation care beds and a minimum supply of oxygen, the mere essential to manage the disease will severely fall short leading to humanitarian crisis of immense proportion. The socioeconomic ripples of unwarranted loss of lives will have abysmal and pervasive consequences not only on victimized families but will create colossal liabilities to the society, the economy and the state. The long term consequences of famine will have exponential impact on the death toll and further economic collapse.

A Module for Application:

This module describes how the persons in a lockdown community having undergone the Rapid Dot Blot Test can be classified according to their immunologic and epidemiologic competencies into **safe to community (Macro-packing) and non-vulnerable, safe to community and vulnerable, un-safe to the community and unknown** identities. They can be accordingly tagged **green, orange, red and black**. These identities can be coupled to a **mobile phone module (application) for ready identification and handling**.

Concomitant application of the antigen/nucleic acid and antibody detection methods compensate for false positives with antibody tests. On the other hand, false negatives with antibody tests hold an orange tag. They either remain with safety in LDC or being antigen negative cause no harm when set free in LFC. There is however a negligible risk with those having concomitant false negative antigen and false positive antibody test. This combination is likely to be rare. Persons with false positive antigen tests may undergo an unnecessary isolation nevertheless to the benefit of the family and the community while oneself remaining safe.

The test can be performed by **mobile community teams** having undergone short training in the same way as the national identity (NID) or mobile phone re-registration was carried out in Bangladesh by home to home service to cut down risk of infection occurring as a result of massive movements for the test. The test is to be carried out sequentially in priority groups taking into consideration their

role and functions in the society, economic relevance, health conditions and age.

Having identified their epidemiologic and immunologic identities the persons with green tags are to be released after a stipulated time to function almost normally in the workplaces and lock free community. In addition to those with green identity, healthy and persons of community and economic relevance with orange identity if volunteering can be incorporated to those functioning normally in the lock-free community maintaining a 70:30 (Green:Orange) proportion in accordance with the herd immunity concept(Micro-picking). **In this case the herd immunity is to be artificially and manipulatively created.** The persons with black and those vulnerable and not currently relevant for restoration normalcy with orange identity are to remain in lockdown at homes and undergo further testing, according to epidemiologic priority, for reidentification and relocation. The persons with red identity are to observe isolation at home or in clinical setting as their conditions may require (Table-1).

Table 1. Showing Person’s identities on the Basis of RIT Results and the Corresponding Decisions

	Antigen Test	Antibody Test	Status to self	Status to Community	Tag	Action
Result	Positive	Negative	Infected	Dangerous	Red	Isolation/Treatment
	Negative	Positive	Safe	Safe	Green	Release Free
	Negative	Negative	Not Safe	Safe	Orange	Lockdown or Elective Release
	Not Available	Not Available	Unknown	Unknown	Black	Lockdown

The further handling of persons with red identity will be based on subsequent testing and formation of newer identity. Students and younger population, those ordinarily home-bound persons (housewives and unemployed) and persons with comorbidity are to undergo testing last unless they show significant clinical symptoms of the infection. All persons in the lock-free community will have to observe personal protective etiquette (distancing, wearing mask and maintaining hand hygiene) and wearing personal protective equipment (especially the orange tagged persons) if their job and movement deserves All in this community will have to remain under active surveillance especially those with orange identity for detection of active or occult infection.

In this way to and fro movement between locked-down and lock-free communities over time will observe shrinkage of the locked-down community and a swelling of the lock-free community. Over a time the entire geographic community will find an exit from the corona trap using the **damage control concept** and **controlled safe movement strategy of immunologically and epidemiologically identified persons.** This can restore normalcy of life and economy (Figure-3).

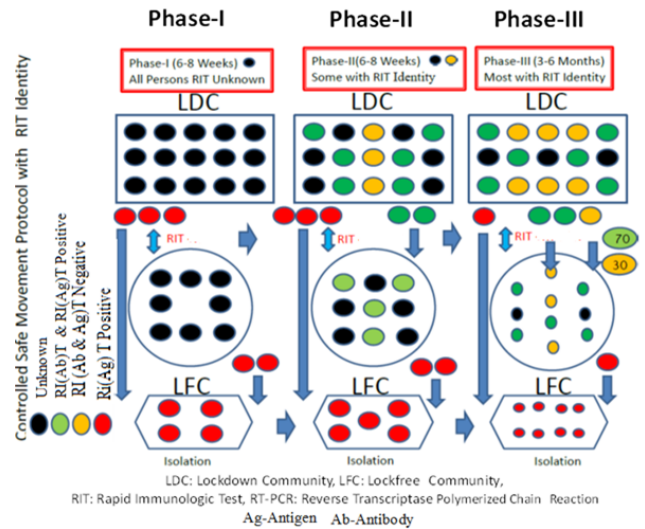


Figure 3. Controlled Safe Movement Protocol with RIT Identity

2 CONCLUSION

The module harnesses idea from the phenomenon of herd immunity that explains the natural remission of epidemics or pandemics by cutting down the rate of transmission when about two thirds of the population naturally acquires the infection and natural immunity to it after submitting the attendant death toll. The idea of herd immunity is used in mass immunization programs by attempting to recruit at least this critical proportion (60-70%) of the population for vaccination to create transmission barriers to the disease.

As a natural phenomenon the time to develop herd immunity is uncertain and unknown. Under the current situation of a highly interlacing global systems of human subsistence, functions and development, the lockdown strategy although effective as a healthcare measure has unrecoverable damaging effect on other constituencies of life including livelihood and economy in the long run.

Therefore, evidence was sought if a manipulative herd immunity condition can be created in the society by identifying those already affected by the disease and currently immune from it along with those not having either any evidence of existing or past infection and therefore not capable of transmitting the disease. It was hypothesized that a throughput mixing of these two populations in 70:30 proportions could provide a herd immunity condition for rapidly reviving vitality of the community.

Having been satisfied with the currently best available scientific evidence, the module describes a design that can create a herd immunity like context manipulatively in the free community through the identification of individuals’ immunological and epidemiological identities through a test that is simple, low-cost, technology void, on-spot in performance and quick in generating reliable results as the dual-acting antigen and antibody detecting Rapid Immunologic Test. The mixing manipulation can be achieved through a

simple management protocol linked to a mobile phone application.

This module outlines a complete way out for overcoming the gruesome consequences of the pandemic early with minimum co-lateral damage by using a best evidence-based, systematic and professional approach.

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