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Unwinding Our COVID 19 Pandemic Safeguards After Vaccination

Ronald G Nahass*[1-3] and Edward J McManus[1,4]

[1]*ID Care, Hillsborough NJ 08844*

[2]*RWJS - Somerville NJ*

[3]*Rutgers University - Robert Wood Johnson Medical School, New Brunswick, NJ, USA*

[4]*Atlantic Health System - Morristown Memorial Hospital, Morristown, USA*

***Corresponding author:** Ronald G Nahass, ID Care, Hillsborough NJ 08844; RWJS - Somerville NJ; Rutgers University - Robert Wood Johnson Medical School, New Brunswick, NJ, USA

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ABSTRACT

Background: The United States is now providing over 2 million vaccines per day. Many are asking how or what should we unwind from our pandemic safeguards as vaccines are deployed. Although the Centers for Disease Control have provided some early guidance there has been an absence of clarity on what processes that were changed to improve safety during the height of the pandemic could be reduced.

Objective: We reviewed the data on vaccine effectiveness and the value of the safeguards that are in place to develop guidance on making changes to those safeguards that are safe and low risk.

Conclusion: The vaccinations are safe and effective and now is the time to begin reducing some of the safeguards. We can safely do this as part of the return to normal.

Introduction

With the deployment of COVID19 vaccine many are wondering when do we get back to normal and what does that even look like? The message since vaccination distribution began has included the need to continue to wear masks because of the possibility of transmission of SARS CoV2 despite the vaccine. Although a theoretical concern we do not have evidence to support that concern for this virus nor do we see that in other vaccines. More recently, data is accumulating that points to dramatic reductions in transmission with the vaccines [1,2]. Accumulating data from the Astra Zeneca vaccine study, the Moderna vaccine study and real-world observational data from Israel provide evidence that the vaccine will reduce transmission [3-5]. There are many caveats around unwinding our COVID19 posture of the past year related to vaccination. These include the variants that may evade the immune response, persons who are vaccine hesitant, and a vaccine not yet approved for individuals under 16 years of age.

None the less as the pandemic progress we move toward the goal of "herd immunity" both because more people are infected and more people are vaccinated, particularly those at greatest risk. In fact, the actual number infected is likely far greater than number reported with some estimating as many as 17 times the reported positive results in the developed world are infected [6]. Recent data on 4 vaccines using 2 different platforms suggest that the protection of the vaccine for people getting seriously ill to the point of needing hospitalization or dying is nearly 100%, including variant infections [2-8]. The protection from actual illness from COVID19 varied from 66 to 95% depending on which vaccine. All these individuals, known infected, estimated infected and vaccinated should be assumed to have immunity. How long that remains is unclear but it appears to be at least 8 months [9]. Although not enough to achieve herd immunity the increasing numbers of vaccinated persons is moving us in that direction. Indeed, the nursing home experience in this

regard is a real-world example of the dramatic impact the vaccine has on disease prevalence in a highly vulnerable population [10].

Methods

We evaluated pandemic safeguard processes in the regional hospitals at which our organization provides care. Many of these processes were mandated by either the Governor through executive order or by rule from the Department of Health. Additionally, based on known methods of transmission many hospitals implemented additional safeguards for staff and patient activity that were designed to reduced risk during the pandemic. These were identified as to activities related to staff and activities related to patient care. We then reviewed available evidence for the benefits of the safeguards and benefits of the vaccine to development guidance on loosening the safeguards.

There are many questions for a health system to answer to provide a safe work environment for staff and for patient safety. These include ongoing testing, exposure protocols, strategies for quarantining, patient and staff vacation and travel policies, and the role and degree of PPE. The evolution of health system processes in the COVID19 era occurred rapidly, and at times with little information because SARS CoV2 was a newly emerged virus. The processes were put into place with the intent of protecting staff and patients while assuring the opportunity to maintain a high level of care to seriously ill patients. We examine the opportunities to unwind or adjust hospital processes from both perspectives.

Results

Management of Staff

Many process changes implemented for staff to mitigate COVID19 risk have severely impacted workflow and routines. These included screening protocols on entry to the facility that may involve thermal screening and questionnaires, mealtime protocols, quarantine protocols on exposure or travel, limits on travel, testing requirements on exposure, and modification to optimal personal protective equipment (PPE) usage protocol. There is little evidence that symptom or thermal screening effectively blocks infected persons from gaining entry to a hospital. Since screening protocols short of testing are insensitive and ineffective at identifying people with mild, early, or asymptomatic infection such staff can gain entry to the building [11]. A fully vaccinated employee is not going to get ill with COVID19 and the concern about transmission albeit not fully known it likely to be mitigated dramatically by both vaccination and mask wearing based on current reports [3-5]. Therefore, fully vaccinated employees should be allowed to skip the line and enter the building without screening. Once the staff vaccine rate achieves a certain threshold (we suggest 85-90%) screening can be reduced to evaluating visitors.

Using a smart phone identification or an RFID embedded in an ID Badge to notify a reader on entry could be easily developed to make the process efficient. Unvaccinated staff should be a small number and should focus on rapid identification of unrecognized infection through twice weekly testing using a rapid antigen test [12]. Concerns for this approach include equity for vaccine availability and privacy rights. Health systems provided universal access to vaccination at no cost within their communities regardless of the role in the hospital. Although certain groups may have higher vaccine hesitancy, the failure to get vaccinated in health systems is not due to the absence of opportunity, availability, or cost. The concern that individuals will be able to be identified as having received or not received a vaccine is a privacy issue that is not consistent with practice for other transmissible agents. For example, it has become routine to require influenza vaccine in most health systems. Individuals who were not vaccinated frequently were either terminated from their position or required to wear a mask. The culture for coming to work ill has been changing. Organizations should evaluate employee policies to be certain they are supportive and that there are no penalties or job risks for individuals who stay home when ill.

Breaktime and mealtime has been recognized as one of the highest risk activities for transmission of COVID and many systems put severe restrictions on meal and break time activities that limited social interaction. Mealtime and break times are important social activities that help team building and camaraderie. We believe that a facility can establish a mealtime routine that allows fully vaccinated individuals to enjoy meal and break time together without the use of masks. The recent CDC guidance on vaccinated individuals provide support for this approach (Ref). Unvaccinated individuals would have to continue to eat and take breaks separately. Exposure management of vaccinated and unvaccinated staff member should be adjusted. The CDC modified its guidance on exposure and quarantine for vaccinated persons to allow vaccinated asymptomatic persons to not quarantine [12]. However, there is a 90-day window after vaccination wherein this recommendation was applicable. After the 90-day window, pending any revision, the exposed person would have to go back to a quarantine process according to the CDC [13]. This 90-day limitation is overly cautious and, in our opinion, should be extended particularly because of accumulating data on durability of immunity [9]. The real-world experience of Israel will further inform this duration decision.

Unvaccinated individuals would need to adhere to the current quarantine and testing protocols consistent with local rules to limit the risk of disease transmission and allow early treatment intervention. Mask wearing will still be required for the foreseeable future in healthcare facilities by both vaccinated and unvaccinated persons while caring for patients. The experience with widespread

mask wearing and social distancing has resulted in dramatic reductions of other respiratory virus including respiratory syncytial virus (RSV) and influenza [14]. As a result, there are good public health reasons to continue this practice even outside the COVID 19 concerns. Keeping the rates of these diseases low in HCW will limit absenteeism and limit risks to patients. Since they tend to be seasonal health systems may consider seasonal use of masking during high transmission months rather than year-round when the COVID19 crisis abates. For the coming year this should not change. The use of other personal protection equipment (PPE) such as universal use of N95 and eye guards by care givers when exposed to patients receiving aerosol generating procedures should not change.

Good PPE for high-risk activities is good practice. Regardless of vaccine status these practices should continue. SARS CoV2 vaccination protocols should follow the model of other high-risk diseases for which vaccination is available. Specifically, the model of influenza vaccination in health systems should be applied in the same manner to SARS CoV2. All health care workers must be vaccinated on the schedule that is ultimately determined to be protective. We propose this to be a mandatory vaccination for all staff. This is needed not only to protect the work force but also vulnerable patients who might be cared for in the institution. Institutional outbreaks of COVID19 in both hospitals and long-term care that were linked to unrecognized infections of staff have been reported [15]. Like with influenza vaccination, SARS CoV2 vaccine should be offered to all at risk hospitalized patients on discharge. This can be modified based on immunity status if routine admission testing for antibodies to SARS CoV2 is adopted and based on the circulating variants and need for booster dosing. The use of the vaccines requiring a single dose may make this easier to accomplish successfully.

Management of Vaccinated Patients

Several areas of process have likewise been altered related patient care activities. This includes routine testing of all admission to a hospital, testing of all patients prior to an operative procedure, and limits on visitors of patients in the hospital. A number of these practices are no longer necessary. Routine testing of asymptomatic patients who have received both doses of the vaccine is no longer necessary. No testing for admission to a hospital and no testing prior to elective procedures would be necessary. If a person is symptomatic testing should proceed as clinically indicated. There may be a role for routine SARS CoV2 antibody testing on admission. There are many routine testing procedures for hospitalized patients including CBC and Chemistry testing which acts as a baseline and as a warning for unexpected clinical disease, e.g., chronic renal failure. The use of the antibody test to make sure a hospitalized patient remains protected for SARS CoV2 can increase the margin of safety for nosocomial transmission in a known congregate setting. It also provides an opportunity to vaccinate a non-immune individual. Health systems should consider routine SARS CoV2 antibody testing on admission. Visitation can be expanded to allow fully vaccinated persons to visit. The visitor must show proof of vaccination. The duration of immunity is unknown at this point and therefore the time over which a dated vaccine card is valid is unknown and will have to be adjusted as more is learned. For now, based on the early results is seems prudent to allow visitation for up to 1 year.

Discussion

These concepts provide a framework for consideration of how to unwind our COVID19 protection stance in the setting of widely available vaccination. It is predicated on adequate supply of vaccine, ongoing evolution of understanding of the duration of immunity and need for booster doses. Challenges to broad adoption come from the unknown, related to the novel nature of the infection and limited long-term information on vaccine risk, durability of immunity and risks posed by variants that continue to evolve. Additional concerns include concerns for equity, privacy, the need for a reliable mechanism to track and verify vaccine status, particularly if repeated or new doses are needed either to combat variant concerns or waning immunity, and the logistics of operationalizing these adjustments to our pandemic stance.

None-the-less, we need to move forward to modify our procedures based on what we do know to lead our communities in the unwinding process. The accumulating evidence indicates that the vaccine indeed will protect for serious illness and provide dramatic reductions in transmission. As a result, restrictions in place can be relaxed for vaccinated individuals. Waiting for 75-80% of the population to be vaccinated limits the opportunity to speed the return to normal. Furthermore, it will add to vaccine hesitancy because if individuals see no material difference in social activity related to being vaccinated, they may see less value to the vaccine. Indeed, we believe adoption of the graded approach we are advocating will act as a form of game theory to encourage more widespread vaccination to gain the benefit of greater socialization. The time to act is now.

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Ronald G Nahass. Biomed J Sci & Tech Res

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