Congenital Heart Disease

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ARTICLE

COVID-19 Vaccine Priority Access for Adults and Children with Congenital Heart Disease: A Statement of the Italian Society of Pediatric Cardiology

Gabriele Egidy Assenza[1], Biagio Castaldi[2,*], Serena Flocco[3], Giovanni Battista Luciani[4], Giovanni Meliota[5], Gabriele Rinelli[6], Ugo Vairo[5], Silvia Favilli[7] and Board of the Italian Society of Pediatric Cardiology

[1]Department of Cardio-Thoracic and Vascular Medicine, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy

[2]Department of Women's and Children's Health, University of Padova, Padova, Italy

[3]Health Professions Research and Development Unit, IRCCS Policlinico San Donato, Milano, Italy

[4]Department of Surgery, Dentistry, Pediatrics and Gynecology, University of Verona, Verona, Italy

[5]Pediatric Cardiology, 'Giovanni XXIII' Pediatric Hospital, Bari, Italy

[6]Department of Pediatric Cardiology and Cardiac Surgery, 'Ospedale Pediatrico Bambino Gesu', Roma, Italy

[7]Pediatric Cardiology, 'A. Meyer' Pediatric Hospital, Firenze, Italy

[*]Corresponding Author: Biagio Castaldi. Email: b.castaldi@yahoo.it

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ABSTRACT

COVID-19 pandemic continues to strike across the world with increasing number of infected patients, severe morbidity and mortality, social life and economy disruption. Universal access to vaccine prophylaxis will be pivotal in controlling this infection and providing individual level protection. However, mismatch between vaccine request and vaccine availability, as well as constraints in logistics of vaccine campaign is creating a transition phase of progressive but still incomplete inclusion of group of individuals in the vaccination process. Selected patients living with chronic and multisystemic disease may present increased propensity of adverse outcome, should Sars-Cov-2 infection develop. In these patients, expedite access to COVID-19 vaccination may be considered. The Italian Society of Pediatric Cardiology National Board is providing a viewpoint to inform policy makers and public authorities during vaccine allocation strategies development, to consider higher priority and expedite access for selected groups of patients living with congenital heart disease.

KEYWORDS

COVID-19; vaccine; congenital heart disease

1 Introduction

The Coronavirus Disease 2019 Pandemic (COVID-19) is still spreading worldwide with increasing number of infected patients, hospitalization with pneumonia and multiorgan disease, increasing number of deaths, prolonged and severe healthcare resource utilization, social and economical life disruption [1]. Significant concern has been raised regarding spontaneous genetic viral variants presenting different profiles of host susceptibility and reported increased prevalence among young individuals and children [2].

Epidemiological data suggest that viral circulation will remain high for a significant amount of time, with sequential phases of spikes and trough [3]. Containing social measures and distancing proved to be effective and should be strongly suggested for patients with chronic and multisystemic diseases with increased propensity to severe forms of Sars-Cov-2 related infection [4].

However, converging data and expert opinion suggest that key control of the pandemia and individual protection will be achieved via active immunization through specific Sars-Cov-2 vaccines.

The first two available mRNA based vaccines have been recently released for clinical use [5,6]. At this stage of knowledge eleven vaccines have gone through some form of approval for clinical use in different countries and are being currently introduced in the clinical arena [7]. Fifty-seven other vaccines are at different stage of development along the pipeline; of these at least 10 are currently in sequential or combined phase 3 stage [7]. At this time no vaccine has been released for use in children younger than 16 years of age, but this may change in the next future as new data on off-label vaccine use and specific regulatory trials may become available [8].

Currently, mismatch between vaccine request and vaccine production and immunization practice does exist in many developed countries, including many European countries [9]. Access to population-based vaccination is severely hampered in developing countries.

As a consequence different strategies have been developed to guide priority access to vaccines throughout the world. In many European countries, including Italy, vaccine allocation/access and immunization practice has been guided by two main decision-making variables: individual age and risk of exposure to Sars-Cov-2 virus [10]. Accordingly, in Italy healthcare workers and institutionalized elderly patients have been prioritized over the rest of the population [10]. At the time of this manuscript drafting progressive opening to specific age-groups and selected social exposed workers (police, military) is being considered and implemented [10]. In the future, with large scale vaccine production, strategic and logistic improvement and multiple vaccines approval, wider, faster and progressively comprehensive access to COVID-19 vaccination is expected. However, data suggest that population-based immunity will be achieved with very high vaccination rate. With the pace of current vaccine campaign, this may be achieved after significant time (probably many months).

During this delicate transition phase, policy makers and health care regulatory agencies may be asked to consider higher priority and expedite access to vaccine for selected group of patients living with chronic and multisystemic diseases that may increase chance for severe Sars-Cov-2 infection clinical course [11,12]. These long list of diseases include oncological, respiratory, and cardiovascular disease conditions, renal failure, immunological disease and others. However, for many of these patients, age itself will allow them to gain priority access to vaccine protection. Conversely, young patients may be precluded by priority access and could be at risk for prolonged time even in a situation where larger vaccine availability could lead to lenient approach.

The mission of the Italian Society of Pediatric Cardiology is to protect and care for children and adults with congenital heart disease. Congenital heart disease (CHD) is a very heterogenous group of cardiovascular pathologies, affecting a broad range of age group (from fetus to old age), different pathophysiology, frailty profiles, and diverse surgical and transcatheter therapies.

COVID-19 syndromes in patients living with CHD have been reported with variable outcome and severity profiles [13].

Access to vaccination for such patients is a very common question during this phase of pandemia from referring clinicians, primary care physicians, parents, teachers, patients and caregivers.

The board of the Italian Society of Pediatric Cardiology grouped together to try to delineate a hierarchical risk profile for severe Sars-Cov-2 related infection in this delicate and complex patient

population (Fig. 1). The board believes that expedite access to COVID-19 vaccine, as soon as feasible, would be strongly advised for patients with any form of pulmonary arterial hypertension (type 1 pulmonary hypertension), Fontan circulation, severe left (systemic) ventricular dysfunction (even more if with progressive symptoms of congestive heart failure/reduced cardiac output), severe valvular dysfunction or severe right and left ventricular outflow tract obstruction, any form of palliated CHD (including Glenn anastomosis, pulmonary banding, any form of systemic-to-pulmonary shunt) in particular if cyanosis is present. Similarly, patients with CHD and unbalanced pulmonary perfusion (left or right lung hypoperfusion/hypoplasia, peripheral pulmonary stenosis, type 5 pulmonary hypertension) should be considered at increased risk of Sars-Cov-2 severe disease and should be offered timely vaccine prophylaxis.

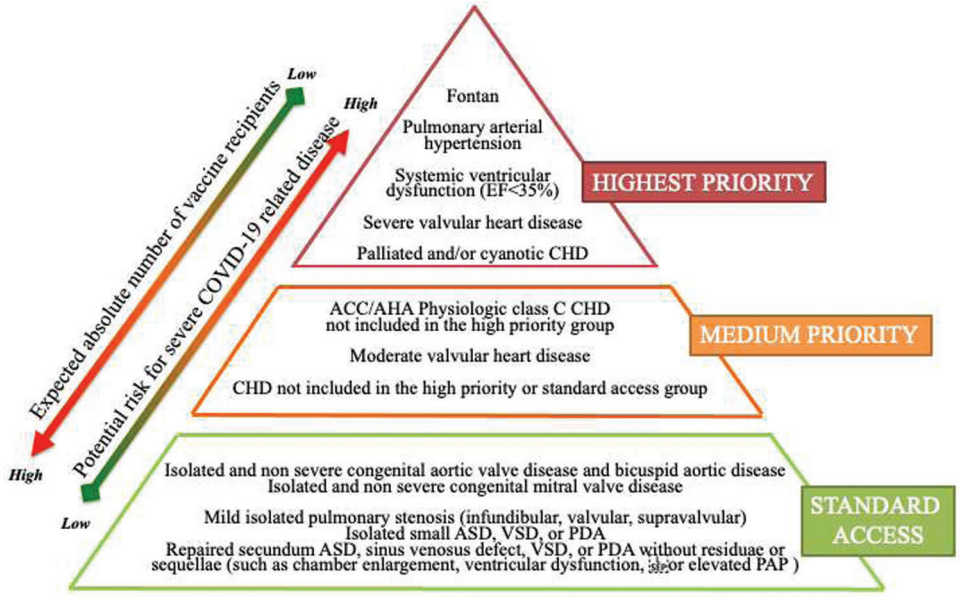

Figure 1: Recommended priority access to COVID-19 vaccination based on the expected Sars-Cov-2 related infection severe clinical course in different group of individuals with CHD. Valvular heart disease encompasses a broad spectrum of cardiac disorders, severity definition should be derived from European Society of Cardiology Guidelines. ASD, Atrial Septal Defect; CHD, Congenital Heart Disease; EF, Ejection Fraction; PAP, Pulmonary Arterial Pressure; PDA, Patent Ductus Arteriosus; VSD, Ventricular Septal Defect

Patients with moderate valvular diseases, significant left to right shunt, systemic right ventricle, repaired CHD with residual defects or surgical sequelae including arrhythmias and, in general, patients classified in AHA/ACC CHD Physiological Class C should have access to vaccination with a moderate priority [14].

Mild valvular diseases, mild left-to-right shunt and corrected CHD without sequelae can be considered for standard priority (Fig. 1).

Patients with CHD and multi systemic diseases, mental disabilities and/or genetic syndromes should be evaluated on case-by-case basis taking into account the synergic effect of multi-organ dysfunction and the reduced clinical compliance of these patients in case of severe COVID infection.

Children have been considered a low risk population both for low propensity to infection and low rate of severe course. Viral variants may change current scenario to this regard. No vaccine has been approved for clinical use in patients younger than 16 years of age. However, should a vaccine be available and approved for children younger than 16 years of age, the board of the Italian Society of Pediatric Cardiology believes

that similarly to what is reported in the Figure, children or infants with CHD should have differential priority access to vaccine, following the same approach we delineated in older patients. Moreover, converging data helped to delineate a specific form of multi-systemic inflammatory syndrome resembling Kawasaki disease in this age group [15]. As a consequence, even in the absence of strong data, expedite or high priority access should be considered for children with history of Kawasaki disease in case of extension of age range for COVID-19 vaccine prophylaxis.

We recognize that our suggestion is largely based on expert opinion and very limited data. We are aware that final decision to vaccine practice policy remains in the exclusive power of public authority in a check and balance decision-making in a very complex and evolving scenario.

Our strongest hope is that our recommendation will be of no utility in the next future thanks to control of the pandemia and universal access to vaccination.

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Conflicts of Interest: The authors declare that they have no conflicts of interest to report regarding the present study.

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