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Safety for all: coronavirus disease 2019 pandemic and cardiac surgery: a roadmap to 'phase' 2

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INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic, caused by SARS-CoV-2, is affecting several areas of the world [1] with different degrees of severity. Italy, in particular its northern regions, which include Lombardy, Piedmont, Veneto and Emilia Romagna, has been the first European country affected by COVID-19.

After a series of attempts to control the spread of the infection with local area lockdowns [2], the prevalence of the infection rose significantly and led to a nationwide lockdown on 9 March 2020.

The COVID-19 pandemic has led the emergency task forces of the 20 Italian regions to reallocate intensive care unit resources, to cancel elective surgical procedures and to allocate intensive care unit beds usually dedicated to cardiac, neurosurgery and some coronary care patients to the care of patients with COVID-19 [3]. Two models have been used to allocate cardiac surgical services. In Lombardy, the Italian region most severely affected by the epidemic, a 'hub and spoke' approach has been implemented. Four of the 20 cardiac surgical units have continued their routine activity (hubs), and the remaining 16 units (spokes) stopped cardiac surgical activity and their resources were reallocated to the care of patients with COVID-19. All the emergency and urgent cardiac surgical cases, as well as patients on the waiting lists requiring treatment within 60 days, were diverted to the 4 hub units [3]. In Veneto, the 5 cardiac surgical units remained operational but were allowed to treat only urgent cases.

Since the second week of April, the COVID-19 pandemic has moved towards a more controlled phase of viral spread. The second phase (phase 2) of the treatment of COVID-19 is expected to begin 4 May 2020 [4]. In addition to the mortality and morbidity caused directly by infection with SARS-CoV-2, the reorganization of acute services has inevitably led to a reduction in the examination and treatment of several non-COVID clinical conditions in the areas of cancer and cardiovascular disease. In addition, some patients are receiving 'second best' treatment, such as coronary artery stenting and transcatheter aortic valve implantation, because surgical treatment is not available. These changes may have led to sizeable collateral damage, including increased mortality and morbidity from non-COVID conditions. A recent report from the British Office of National Statistics estimated that up to one-third of the extra deaths recorded this year compared to previous years are from causes other than COVID-19 [5].

Health care communities need to develop a strategy to restart non-COVID medical and surgical care. To achieve this goal safely, they need to develop a 'roadmap'. We describe a possible way to start phase 2 in cardiac surgery. Our strategy is based on achieving the following 2 goals: (i) given the geographical heterogeneity of the epidemic, assessing the level of spread and severity in any given area and (ii) developing a COVID-free pathway to mitigate the risk of nosocomial infection. Because it is beyond the scope

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of this manuscript to cover all eventualities in detail, our goal is to provide general principles to inform local strategy when approaching phase 2.

ASSESSMENT OF LEVEL OF SARS-COV-2 SPREAD AND SEVERITY

Knowledge of the prevalence of COVID-19 symptomatic and asymptomatic infections in the whole population at the country, regional and subregional levels, as well as virus epidemiological hallmarks such as incubation time, persistence and relapses remains limited. However, substantial geographical differences in terms of incidence, prevalence, infective index and case fatality rate in Italy are apparent, a picture mirrored by data from other countries [6]. Given that starting phase 2 would be advisable when the epidemic is more under control in order to free up more resources and reduce the risk of nosocomial infections, these criteria may be met at different time points in different regions and provinces.

We have designed a mathematical equation to calculate a COVID-19 Spread and Severity Index (CoSS), to ascertain if a region or geographical area is at a high, medium or low risk of COVID-19 spread and severity at any given time (Fig. 1). The algorithm is based on the daily available data published by the Italian Ministry of Health, which describes the prevalence of patients positive for COVID-19, the numbers of hospital discharges, deaths, nasopharyngeal swabs performed and the ratio between the number of nasopharyngeal swabs performed and the resident population [7]. The algorithm is the ratio between the total number of deaths and the number of recovered patients (an index of severity and lethality that intrinsically accounts for virus characteristics and also for the availability and allocation of critical care resources) multiplied by the incidence of new regional cases in the last 2 weeks (2-week new cases/total regional inhabitants). This regional and subregional score of the severity and ongoing spread of COVID-19 has been indexed to a baseline score of 0.000032 (mean value of the low-score regions). The indexed regional or subregional values can be classified into 3 categories according to the following score intervals: <5, low risk; between 5 and 10, medium risk; and >10, high risk. We recommend that the risk be reassessed every 2 weeks, because changes in the epidemic may affect the status of the individual region or province. This score is intended as a guide and could be estimated also at the level of the institution, taking into account the population catchment area. We recommend starting phase 2 in regions/provinces or areas with a low CoSS index. In areas where the data needed to calculate this score are not routinely available, we recommend liaising with the local public health authorities to obtain an estimate of the status of the epidemic.

$$CoSS\ Index = \frac{\left(\frac{Deaths}{\text{Recovered patients}}\right) * \left(\frac{\text{2-Week new cases}}{\text{Total inhabitants}} + 0.0000000001\right)}{0.000032}$$

CoSS: COVID-19 Spread and Severity Index

CoSS Index = CoSS of region or province

Deaths = Total number of deaths per region or province

Recovered patients = Total number of recovered patients per region or province

2-Week new cases = Recent 2-weeks new cases in region or province
Total inhabitants = Total inhabitants of region or province

0.0000000001 = Correction factor

0.000032 = Mean value of the low-index regions (data from 7 - 20 April 2020) (this information can be updated)

Figure 1: CoSS calculation. CoSS: COVID-19 Spread and Severity Index; COVID-19: coronavirus disease 2019.

DEVELOPMENT OF A CORONAVIRUS DISEASE 2019-FREE PATHWAY

The development of a COVID-19-free pathway necessary to reduce the risk of infection to patients and staff and the morbidity and mortality associated with it, requires a definition of the setting, measures to screen patients and to protect staff, risk management and governance.

Setting

Although some areas have used the 'hub and spoke' approach whereby hospitals delivering cardiac surgery are not routinely treating COVID-19 patients, the focus and the challenge during phase 2 are the reconversion of the cardiac surgical departments where resources had previously been redeployed for the treatment of infected patients, the most common approach adopted in Italy during phase 1. The reconversion, a dynamic process, needs to be part of a hospital-wide approach. Decisions made today may be different from those made only a few days later under these rapidly changing circumstances. Given that these institutions will continue to care for COVID-19 patients, we recommend that clearly separated pathways in COVID-19-dedicated and COVID-19-free areas are developed within the hospital. In addition, there is a need for an area reserved for patients of unknown COVID status who are awaiting testing and results. For simplicity, we have designated these areas red, white and grey, respectively. A patient is defined as being COVID-19-free (or presumed so) after being adequately screened, taking into account that up to 40% of patients could be asymptomatic while still being infective, particularly in areas where the impact of the epidemic is still high. At the time of this writing, there are no reliable tests to identify those who have developed antibodies to SARS-CoV-2. Therefore, we propose to attribute a COVID-negative status in the following circumstances:

- Self-isolation for 14 days before surgery.
- No history of contact with COVID-19 positive family members or patients for 14 days.
- No history of contact with family members displaying COVID-19 symptoms in the last 14 days when self-isolating.
- No symptoms of cough, sore throat, anosmia or high temperature.
- Clinical and biochemical parameters within normal limits, including O_2 saturation in air >94% (unless pre-existing lung conditions), apyrexial, normal white cell count (including lymphocyte count), normal levels of inflammatory markers and normal results from a liver function test.
- Two consecutive (24 h apart) negative results from COVID-19 polymerase chain reaction nasopharyngeal and oropharyngeal swab tests (please note that there is a significant false negative rate in some PCR tests).
- Clear computed tomography (CT) scans of the lungs.

The use of CT scans is necessary to increase the accuracy of results from nasopharyngeal swabs in identifying asymptomatic patients particularly in areas with high infection rates [8] because these contribute significantly to the spread of the disease [9]. However, where the impact of the epidemic is decreasing and with the development of more accurate testing including antibody tests, CT scans may no longer be necessary. Patients who meet the preceding criteria could be admitted and treated in the 'white' areas in a routine fashion. Inevitably, there will be patients admitted to the hospital requiring urgent or emergency treatment for whom the COVID-19 status is unknown. These patients should be admitted to the 'grey' areas, which will require an appropriate infrastructure for isolation. If the clinical status of these patients allows time for completing the necessary screening tests, the testing should take priority and then the patients should be triaged accordingly. Red areas are reserved for general COVID-19 positive patients.

Patients who are negative for COVID-19 should be treated following the 'white' pathway. The appropriate treatment strategy for COVID-19-positive patients should be decided on a patient-by-patient basis using the heart-team approach.

Patients with unknown COVID-19 status with life-threatening emergencies or who tested positive for COVID-19 should be treated with all precautions to minimize the risk of infection for the patients and others.

With time, the numbers of patients within these institutions who test positive for COVID-19 will decrease, and resources for COVID-free patients will be freed up. We recommend that during this phase, COVID-19 facilities be concentrated and co-located away from the remaining areas as soon as it is feasible. In addition, the areas previously utilized to treat COVID-positive patients should undergo appropriate cleaning and disinfection before being redeployed to routine practices [10].

In settings in which cardiac surgery is delivered within institutions not routinely admitting COVID-19 positive patients, only white and grey zones are necessary.

All hospitals should identify dedicated investigation pathways and outpatient and rehabilitation facilities to cater to patients who have recovered from COVID-19 and for the postoperative rehabilitation of patients.

In regions where it is possible to maintain the hub-and-spoke approach, particularly those with high spread and severity of infection (CoSS >10), it should be the preferred arrangement until the epidemic is under control.

Areas at medium risk based on the CoSS score or on information from the local public health authorities should consolidate resources as they become available and move towards a gradual reintroduction of cardiac services.

Principles for protection of health care personnel

Cardiac surgical procedures are at high risk of contaminating staff and should be considered as aerosol-producing scenarios given that aerosol-producing manoeuvres are common. These include median sternotomy, endotracheal intubation, manipulation of the oesophagus with transoesophageal echocardiography and the use of the cardiopulmonary bypass heat exchanger.

With this in mind, the issue of the protection and safety of health care staff becomes of paramount importance. At the time of this writing, data from Italy show that nearly 20 000 health care workers have contracted COVID-19, comprising ∼11% of the total general population infected [11].

Governmental and professional organizations have published guidelines on best practices for using personal protective equipment (PPE) during the COVID-19 pandemic [12]. Furthermore, the procedural steps for donning and doffing airborne-contact PPE in a standard patient room or emergency department setting are described for COVID-19 and other types of virulent microorganisms [13]. Although there are no specific guidelines for donning and doffing sterile PPE in an operating room environment, standardized procedures should be developed locally and paired with education and training for health care worker safety, especially for personnel at high risk of exposure to SARS-CoV-2 [14].

Although it is beyond the scope of this manuscript to describe in detail the types of PPE to use in different circumstances [15], we recommend the use of the most protective PPE available when operating on patients with known COVID-19-positive status or patients with unknown status.

A framework of sharing good practices and lessons to learn should be developed and ideally co-ordinated by the associations of specialists at national and international levels. The University Hospital of Padua, which is in an area with a high prevalence of COVID-19 infection, implemented the early adoption (since 23 February 2020) of the use of appropriate PPE, associated with an educational programme to minimize nosocomial diffusion of SARS-CoV-2. This programme was successful in keeping the infection rate of the health care workers below 2% (Table 1), which compares favourably with the national data indicating that up to 20% of health care personnel are infected at any given time [16].

RISK MANAGEMENT AND GOVERNANCE

During a pandemic, clinical pathways and decision-making are necessarily different from the everyday routine, and *ad hoc* standard operating procedures are developed to meet local needs. We recommend that decision-making processes be well documented and transparent. The heart-team approach remains an important tool to direct the best treatment strategy for the individual patient. Given that social distancing rules are likely to remain in place for a considerable time, facilities for regular virtual meetings should be available. We have proposed herein an approach to restart cardiac surgical services aimed at mitigating the risk of infection. Although this plan is based on the best available international knowledge, there is no orthodox scientific evidence base underpinning our proposed approach. We therefore recommend that individual institutions and local health care communities adopt prospective data collection to monitor outcomes, apply standard risk management protocols to deal with ensuing issues and establish appropriate forums to disseminate lessons to learn and share best practices.

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Table 1: SARS-CoV-2 status of personnel of Azienda Ospedale-Università di Padova (21 April 2020)

Personnel	*n*	SARS-CoV-2 positive, *n* (%)	Hospitalized	Recovered, *n* (%)	Total cases, *n* (%)
University physicians	241	1 (0.4)	0	6 (2.5)	7 (2.9)
Hospital physicians	762	5 (0.7)	0	9 (1.2)	14 (1.8)
Residents	1709	5 (0.3)	0	29 (1.7)	34 (2.0)
Nurses	2891	16 (0.6)	0	25 (0.9)	41 (1.4)
Nurse assistants	1040	11 (1.1)	0	14 (1.4)	25 (2.4)
Other personnel	1408	6 (0.4)	0	11 (0.8)	17 (1.2)
Total	8051	44 (0.5)	0	94 (1.2)	138 (1.7)

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