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COVID-19: Challenges and Management in Italy and Lessons Learned

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a message to others because we realised that perhaps we had underestimated this, and maybe the world was underestimating this. The European Society of Intensive Care Medicine sent out a letter telling everyone to get ready because this was not the regular flu.

What, in your opinion, is the danger to the general population? We know it affects the elderly, and people with a low immune system, but what about the risk to the general population?

It is a mistake to think that this is affecting only the elderly population. COVID-19 can affect all parts of the community, but the older people are the ones that are getting the disease in a worse way. If you're older, you are more likely to get very sick from this compared to if you're younger. But in a society when you're facing something that does not have a specific cure or a vaccine, every citizen is responsible not just for themselves, but also for other citizens. If we believe that we're working in a society that is taking care of each other, we cannot just accept that this is dangerous only for older people and let them become infected. Overwhelming the capacity of hospitals is dangerous for everyone. This disease is indeed affecting more older adults in terms of becoming very sick and dying from this disease, but that should not be an

Doctors say that if they had known about the seriousness of COVID-19, they could have been better prepared, and the world would not have wasted the three weeks China gave them to prepare. What is your opinion?

We could probably have used the time that China gave us to prepare a better surge response. We were still tracing contacts. Nobody was ignoring this, and people were being quarantined, and there was contact tracing. Despite that, clearly something skipped through the filter. The World Health Organization (WHO) has to be praised for the work they were doing

in telling us to be careful because these epidemics can become a pandemic, and that is what happened with COVID-19.

We were surprised by the magnitude of sick patients that could come to our healthcare systems during an uncontrolled cluster. That is what we were fighting day and night. From the moment we realised there were patient clusters in the area, we had to make new beds. We had engineers in the hospital building new units. It is true that if we could forecast, we could have increased our capacity earlier. And indeed when we realised this in Lombardy that the numbers are so high, we sent out

excuse not to control the virus transmission. Nobody benefits from a system that is reaching saturation, whether you're young or old. It was very responsible for all countries that decided to control virus transmission. You can argue that some countries were a bit faster or a bit slower compared to others. Still, the majority understood the message that you're not going to win this by only increasing your capacity in hospitals. You have to control the virus transmission. Therefore, we have to protect the young and the old, and we need to protect the old from getting the disease.

South Korea was very aggressive with its testing and contact tracing. Do you think other countries should have done the same?

I'm not a public health expert. I've been in the middle of this pandemic now for a couple of months. After speaking with public health experts, I can tell you that one recipe cannot be applied to every country, and the same strategy cannot be applied for the same moment on where you are during the pandemic. Even in Italy and in Europe, before we had these clusters, we were doing PCR swabs and aggressive quarantine on specific cases that were COVID-positive. In the beginning of February, there were three cases in Italy, one case in Germany, etc. These were not huge numbers and you could put a whole organisation around those cases to contain them. You have to be very aggressive with that, and if your strategy is controlling the transmission that way, you should carry on doing it.

But in Italy, at least in Lombardy, our cluster is very different from what was happening outside China up to that moment. I remember it was the 20th of February in one of the intensive care units in the region, and a young patient in his 30s tested positive for coronavirus. This patient had no risk factors for having been to China or for having been in contact with somebody from China. There was

no reason to think that the patient could have been a coronavirus patient, but he was not responding to typical pneumonia treatments. The intensivist conducted the PCR swab test, and the patient tested positive. Up to that moment, we were using the same strategy used by South Korea and other countries, but we realised that the filter had not stopped the transmission and that we had a big problem because there was a patient in his 30s in intensive care. We know from data coming from China that the case fatality rate for young people was very low, and we know that it was affecting more older people. But when your first patient that you cannot trace back to other patients is young and in intensive care, you realise that you have a bigger problem. Of course, you try and trace it back and quarantine people, but your strategy has to change. It cannot be the same when you only have a few cases, or when you have a lot of cases.

We are now at the peak of the pandemic here, and we are moving towards Phase two. We cannot have the same strategy of Phase one. Hence, it's important to apply different strategies to contain and control the virus transmission, depending on where you are on the disease. The ideal situation is that you don't have any transmission at all. But we know that for a virus that doesn't have a vaccine, this is probably not possible in Europe. Public health measures have to be in place to try to control the transmission as much as possible. If you cannot suppress it and have a cluster, you may have to use different strategies and choose to lockdown. It's a very painful strategy for society and the economy, but it would not have been possible to do anything else at this stage because the number of cases was high.

Should deaths in hospitals in patients with comorbidities, and with COVID-19 be classified a COVID-19 death? Is that a safe assumption?

People are saying that a patient may have died with COVID-19 and not because of COVID-19. I would argue that you can refer

to that only if you have an asymptomatic patient that dies, as in a car accident, but by definition if you're dying of a clinical deterioration and if your clinical deterioration is due to respiratory symptoms, I really don't care if you started with heart failure or chronic kidney disease. You are now getting a chest infection out of COVID. We know that you're starting from a very low baseline over the physiological reserve. However, I would argue that you're still dying because of COVID even if you're 90 years old and have a lot of comorbidities. That's exactly why society has to protect its old people; otherwise, we run the risk of making these assumptions that because you're old and frail with comorbidities, if you get COVID, maybe you were dying anyway. It is possible, but if you're dying with some symptoms that are traceable to COVID like respiratory symptoms or failure, I think it will be a big jump to say that you've died with COVID and not because of COVID. This assumption that people are dying with COVID and not because of COVID is not correct. If you die in a car accident, and you were having COVID, then you're not dying because of COVID. But if you're dying with a chest infection, and you had comorbidities, you're old, and this chest infection is because of COVID, I would argue that you're dying with COVID even if you have a lot of comorbidities.

Should chances of survival be the criteria for allocating life-saving resources in case there is a shortage?

As an intensive care doctor in Italy and as the President-Elect of the European Society of Intensive Care Medicine, I believe we must give intensive care to anyone who needs intensive care. This is true when you have one free empty bed and when you have 1000 free empty beds. We don't want to reach a situation where we don't have enough beds and have to make choices that we don't want to make. It is important to realise that this virus is something that you don't win just in hospitals, but you

win with citizens, with self-isolation, with lockdowns, with suppression, and with mitigation manoeuvres. We're asking the help of citizens because we want to give intensive care to whoever needs intensive care. This is what we've done in Italy, and this is what doctors are trying to do worldwide. We need the help of citizens to make sure that we don't get an uncontrolled wave of sick patients coming into our hospitals. If they don't help us, we could reach a stage in which hospitals are overwhelmed.

Our hospitals have been stretching. We made an enormous effort in Italy to increase our capacity in ICU. In Italy, age was not the risk factor to come to intensive care. Our median age was 63 years, which means that half of the population was older than 63 and half was younger. But to admit everyone that we thought would benefit from intensive care, we had to increase our intensive care beds. We had to bring intensive care outside of the wards. This is not just being done in Italy. I speak with colleagues from Spain, from France and America. Everyone is trying to increase the intensive care beds where you can do invasive mechanical ventilation, and provide CPAP and non-invasive support.

In the region where I work, we started with 720 beds for intensive care for about ten million people. When we reached the peak of intensive care COVID-19 positive patients' occupancy, we had 1500 intubated COVID-19 patients, and we treated nearly 4000 patients. Outside the intensive care walls, we created a high dependency unit - a level two intensive care - to provide CPAP and respiratory support, non-invasively in which we worked together with internal medicine doctors and pneumologists. That accounted for another 2000 beds approximately. Therefore, we moved from 720 beds for respiratory support in the region to 1500 mechanically ventilated for COVID, and another 300 for other pathologies and another 2000 for CPAP. If you do the math,

we increased our capacity from 720 to 4000, which is five-six times our pre-ICU capacity. This is the effort that people have made to treat every emergency in the region. This is the only choice that we decided to make. However, this would not have been enough if there had not been containment manoeuvres and lockdown in the region.

My two messages to everyone around the world is to increase your ICU capacity and hospital capacity because we want to give intensive care to whoever needs

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intensive care. But don't expect this solution to work only by increasing your capacity by four or five times, which is already an incredible number. You also need to work with public health authorities, and citizens have to work with us to allow everyone to receive treatment. This virus is something we've never seen in our career. It can give you severe respiratory symptoms and can be transmitted easily from person to person. If you don't control the transmission outside of the hospitals, you can really overwhelm any healthcare system in the world.

Different treatment strategies are also being proposed, and many of them are not backed by any clinical evidence. Do you see any strategy that would be effective?

The strongest evidence that we have at the moment is supportive care. We've learned

over the years how to provide ventilation and oxygen to our patients in a way that protects their lungs. We do not cure with our machines in intensive care but rather buy precious time for patients to get better. We are giving time that those patients would not have without our work and without being connected to a machine that we have to know how to use. I would really like to stress this. Everyone talks about ventilators and shortages. The biggest drama is not the lack of ventilators. The biggest problem is finding a way to bring competencies that are required in ICU by intensivists and ICU nurses to so many new ICU beds and patients. You have a much larger team of people that have never worked with these devices and these patients. You have to try to teach them, supervise them, and work with them as a team. Everyone has gone the extra mile around the world. There were doctors and nurses who have never worked in intensive care and who came to help. We were very grateful to these people, but we had to find ways to teach them in a very short period of time how to use these machines and how to have our expertise for a large group of patients. That has been the biggest challenge, much more than any machine shortages. Don't expect that just by bringing 3000 ventilators, you will solve the problem. People, as always, are the most important resource in any crisis. Healthcare workers have been the most important resource that we have had to find in this crisis.

We have to buy precious time by giving support - what we call protective lung strategy. This means giving time on the ventilator but avoiding the ventilator to cause harm. Imagine the ventilator as a machine that brings air with pressure and oxygen to the system. It could be like a caress or like a punch. We don't want to punch the lungs - we want to caress the lungs so that they don't get damaged from the ventilator. It requires a very fine balance to do that. Also, every

patient is different. We have to find ways to individualise the therapy in a large volume of patients. By providing supportive care, we're giving the best chances for patients to recover. We are also giving them nursing care, mobilisation, sedation, nutrition - everything that we can do in terms of support.

Many drugs are being tried, but so far, no drug has proven to be effective and safe. An important thing to remember is that when we use treatment, everyone focuses on efficacy. But we need to think about safety as well. You may hear people say this patient is sick, and we should give this drug. If it works, the patient gets better, but if it doesn't, we have nothing to lose. I'm not so sure about that. We don't know if the drug, when it is not effective, could actually be unsafe. It's a very dangerous assumption to give something just because it's available without studying the profile of these drugs. It's very difficult during a pandemic. You get a large number of patients that you didn't know before, in terms of disease, and there is pressure from the system to try to do the best for these patients. But we have to be very careful. We may do harm if we use treatments for everyone without trying to be precise in what we're doing. The last decades have been all about precision medicine, whether in oncology, haematology, or intensive care. We have also talked about characterising phenotypes. But what we need to do is to understand who the patient is in front of us and understand the physiology and using supportive care in the most precise way. When it comes to drugs, we have to be very careful. We have to find ways and not lose time, but we have to do it scientifically. We can't start using drugs without testing these drugs against a control group and without seeing if there is a cause and effect of what we are doing. It can be very dangerous. We need to find the right balance between doing and learning. It's

not just about the efficacy but also about safety and we need to balance these two things when we try new treatments in our patients.

How close do you think we are to developing a vaccine?

I'm not an expert on vaccinations. There is a lot of research going on in different parts of the world. I suspect it would be unrealistic to believe that we could have a vaccine so soon. It will take a few months, maybe a year. We don't have time to lose because we don't know how long this virus will stay with us. Different countries are preparing for Phase two, and we have to see if we have to manage secondary peaks. We have to assume that this is something that could stay with us a bit longer. I do hope not, but we have to be ready, and this means that we have to carry on working on a vaccine, and other strategies. We need to study new drugs, and we must accept that it could take months before we have something proven to either prevent the disease or treat it. We have to be fast, but that doesn't mean that we have to be faster than what's necessary to develop our strategies in a safe way.

Do you think that there could be a second wave?

We don't know but we cannot afford to be unprepared the second time. I don't think we can afford that for our citizens, our patients, and our healthcare workers. We have to prepare for a second peak. Hopefully, we will not have it, and hopefully, we will do things better, control the virus transmission, and hope there are no secondary peaks. But we need to be prepared to manage these secondary peaks. We have no excuse now. You were asking me before if we wasted time when the virus hit China. If I could go back, we would try to prepare better. I'm sure that is something that every doctor and every healthcare system will tell you now. But if

that was true in February, I don't think we can afford not to be prepared when we release lockdowns.

Do you think the healthcare system has failed healthcare workers and could have provided better support?

It's a very difficult answer to give because the principles are worldwide principles that the WHO is sending out to everyone in terms of which masks to use, which gloves to use, which protection to use for different situations. But in any protocol or guidance, it is the local leadership that puts these things in place. When I realised that there would be a wave of patients in my hospital, I called the simulation team of the University to put together simulation in-situ to train everyone. We trained 80 people in 48 hours about donning and doffing procedures, protective equipment, proning, and incubations before we got the wave of patients. So far, in my team, no one has an infection while working in the COVID-19 ICU units, because we are using a high level of protection. Not in my hospital, but some doctors have died. They seem to be a bit older, and maybe they had been in contact with infected patients without knowing. It is a tragedy, and we are very sad for all the colleagues - not just doctors but also nurses and other healthcare workers. We've all been scared to get the disease. We've been scared to pass the disease to our families and to our parents. It's not been easy, but I would say the recommendations are out there.

You need strong leadership in your country, but you also need strong leadership locally to make sure that you protect your team and that hospitals protect healthcare workers. Speaking for my team, I felt very protected from my management. They worked very closely with me and accepted all my recommendations on how to protect healthcare workers. We've all been very stretched, but because I was focused on protecting my team and the team of the emergency areas where the most invasive

procedures take place, we decided to put an extra effort. We monitored the people that are helping in the most difficult areas. It is important to feel protected in your own hospital and to see that there is that passion and that effort to protect healthcare workers. The recommendations are out there, but how effectively you apply them in your practice is down to local leaders. We need to use simulation for training as much as possible. There's not enough training for this because no one can get used to working with this protective equipment and with these suits. It's a completely different way of working. We cannot afford to have healthcare workers that become sick because of the work that they're doing. It's very important to use as much training and simulation as possible.

In Italy, doctors have also developed a Coronavirus ICU network. What's the goal of this network? What are the experiences or lessons?

There are different networks. I can talk for the COVID-19 Lombardy ICU Network. This network is probably one of the reasons that allowed us to buy extra time in the first two or three days. When we realised we have a cluster and secondary transmission, we knew there was a big problem. No one had prepared isolated units. This network was in place before COVID-19 for providing VV-ECMO and VA-ECMO. It is a network that was put in place by Antonio Pesenti of Policlinico and Alberto Zangrillo from San Raffaele. The network was created to help each other if we have a patient with a severe respiratory failure that requires VV-ECMO or admission that requires cardiac support for VA-ECMO. We coordinated in less than 24 hours from the first case to immediately identify hospitals that could manage the initial surge of patients. Every time there was a positive case in one hospital, we would bring them into the isolated unit. This gave hospitals the time to get organised because containment is important not just in the community,

but also in hospitals. We cannot afford for hospitals to become clusters.

It is important to separate the COVID-19 pathway from the non-COVID-19 pathway because other emergencies are still going on. The network allowed us to have space for whoever needed intensive care. The mission was to create beds for intensive care. It was not just for COVID-19 but to manage all emergencies. We reorganised our emergency network into hubs and

the biggest drama is not the lack of ventilators. The biggest problem is finding a way to bring competencies that are required in ICU by intensivists and ICU nurses to so many new ICU beds and patients

spokes so that we could still care for every emergency, whether it was trauma, stroke, cardiac surgery, myocardial infarction, and so on.

The network is really the most important thing that we had in place to help each other. Patients that were coming to a cluster hospital with no beds were still receiving intensive care by being transferred to a unit that had space. Every time we had space, we were calling back the coordinating centre to inform them in case they had a patient that needed a bed.

I am also a part of this network, and I am in the clinical and technical Scientific Committee of the region. I'm helping and working very closely with Giacomo Grasselli, and Antonio Pesenti, and we advise and help each other.

How can quality research be conducted in times of a pandemic?

We should not forget the basics. We have so

much to learn from a new disease by just observing it. The ICU Network has put a huge effort in disseminating the results and sharing data. Also, the clinical community is doing the same through journals that have decided to open full access. Data is being shared across the world by health authorities and by doctors through social media. It has been a very unifying moment for the clinical and scientific community. Sharing information about what we are observing is very important, but we have to be careful that we don't forget the scientific methods of observations. Epidemiological observations are equally important now, and to know the rate of mortality for intensive care patients. This can inform you about policies and planning. The immunological and inflammation profile of the patient is also important. The more we know about the virus, the more we can find a way to do precise tests and research in an effective way. Despite the stress on the system and the emergency, we must not lose sight of a good scientific method that starts from observation, from realising which phenotype may have a possibility for treatment and then to test the efficacy and safety of this treatment. Some ongoing trials in the UK and America are very interesting, especially the new trials with an adaptive design. We have the tools; we just have to decide how to use them.

Do you think this will be over soon?

In life, you cannot decide what is happening to you, but you can decide how you react. I hope we are managing COVID better now, but we have to be prepared in case it stays with us for longer. We cannot afford to be surprised twice by COVID. We all got a surprise once, but if we release the lockdown and something happens, we need to be in control to protect our citizens, our patients and our healthcare workers. ■