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ITALIAN CLINICAL ENGINEER EXPERIENCE DURING COVID-19

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Umberto Nocco: It's a pleasure to be here and to share with you some of the things we've been dealing with for the past month, actually, because it hasn't been longer than that. Lombardy is the region in the northern part of Italy where I live in. It's been one of the most struck from the virus inside our state. Basically, data shown today shows that we have some 30,000 cases among the 70,000 gross numbers throughout Italy. This happened basically in three weeks. Patient one, as we call him, was found positive on February 21st. Since then, we add an exponential incremental ratio of known patients basically based in kind of a defined area throughout the region. But later on, the outbreak expanded over the entire nation.

The point is that the rest of Italy aside Lombardy seeing cases after two weeks from the start in our region, so that at least they had the time to get ready to some extent before the outbreak reaches them. Of course, we all wish it doesn't happen, but it's an option, of course, that this might end up having quite a number of cases.

Just to give you an idea, the difference between Lombardy and Rome, for example, although I'm saying they did a great job, they had the time one week, not very much, to remodel a closed hospital to accept COVID-19–positive patients only. While in our region due to the birth and the continuous flow of patients to the hospitals, we had to work day by day and try to find out the solution to have them inside our hospitals.

From an HTM point of view, I would like to outline three major problems:

- 1. Machine availability plus space inside the hospitals (e.g., ICU beds).
- 2. Organizational issues.
- 3. Acquisition problems for devices.

One of the main problems we had to cope with was that the need for ventilated beds, not only did we use ICU beds which were more or less full because of standard patients. We were just running normal routine, and we are normally running at 95% better in Lombardy and I think that more or less the same number throughout Italy, but we had to define new areas where positive patients were to be placed.

The more patients, the more ICU beds were needed. Those that could create new ICU beds out of nowhere



did so, while other suffered the way even and they had to figure out a place where to put them, whether it be a normal ward, or some hospitals are starting to put tents outside the hospital at least to do the first screening when a patient comes in with the ambulance or with their car or however they get to the hospital.

This means that the major issue about acquiring technology is basically on four to five types of assets. I'm talking about continuous positive airway pressure systems, ventilators, monitors, infusion systems, and beds being the last and the easier to describe and with difficulties to be found on the market and to be acquired. Although, in the end, we ended up using normal ward beds even if we are to handle intensive care patients because, in some places throughout our region, we are basically a war zone. It's really whatever you have available, that's fine for the patient.

ITALY: THE MOST IMPORTANT DEVICES NEEDED

Umberto Nocco: The point is that if you get the continuous positive airway pressure system, they are the first line because patients come in with some sort of breathing problems. You might use noninvasive ventilation but usually requires a mechanical ventilator which is precious because we don't have a lot of them. We immediately swapped to continuous positive airway pressure systems.

These can be used outside the ICU, especially if you already have training personnel like in lung department or other specialties or medical departments. But you have to be aware that you are risking a lot more aerosol spreading outside the system rather than with the invasive ventilators. We have come to the point where we are making basically our own gas blenders because vendors can't keep up with the need we have.

When it comes to ventilators, if you ask an anesthesiologist, he will ask for the top quality of the product. The point is that we had so many patients that we have become greedy rather than specific, if you see what I mean. We had to acquire devices really fast. The typical call we used to make a couple of weeks ago was calling the vendor and saying, "How many ventilators do you have in stock that can you bring me, say, tomorrow?"

What we had to consider especially devices that could run without compressed air since we don't usually have that in ward. If you end up installing ICU beds in what yesterday used to be normal wards, of course, you don't have all the facility you may have in an ICU as usually defined. Of course, I don't know how many of you are familiar with the Italian way of setting up at hospitals. We usually don't have a room for the patient regardless of his type of treatment that goes from the ICU to the general ward before he goes home. We have specific areas of the hospital dedicated to a different level of intensity of care we have to give to the patients.

The next kind of asset we need to acquire really fast and in good big numbers were monitors and monitoring systems. They are, of course, important for an ICU but also for patients who are taking care in normal wards. General conditions that we want to monitor are oxygen saturation, which is probably the best for a meter to look at, together with CO2, to figure out whether the lungs are working correctly. But they asked for monitors rather than simple telemetry systems because they want to be able to view the monitor without going too close to the patient. So they avoid getting dressed up with protection clothes and breathing all the aerosols, which is, of course, one of the major issues.

As far as I figured out in this past three weeks, you don't need a high-level monitoring. You don't need a lot of parameters. Basically, basic parameters: pressure, of course, invasive pressures because the more the patient becomes bad and more ill, the more you may need to have some invasive pressure, and plus CO2 monitoring unless you have it on the ventilator, of course, because you need to be really aware of the condition of the oxygen exchange in the lungs.

The point is that we needed a lot. In my hospital, we have in standard conditions, some 50 intensive care beds. We've come up to almost a hundred. We basically doubled the number of ICU beds in the hospital to handle this kind of patients and you have to be aware that the hospital I work in, it's not one of the most involved in the outbreak. We have a lot of cases but not as many as in other parts of the region.

The last thing is the infusion systems, both syringe and IV lines. The thing is you never know how many you need. At least, that's what happened to me. If you talk to different anesthesiologists, they may ask you for different numbers. I wouldn't be able to say the correct number, but probably a gross number is something around four pumps per patient, but the problem is always the same.

We're talking about 20, 30 beds at the time, so numbers go up real, real fast. In Italy, at least, we don't have a sort of organization where we have stocks of medical devices that can be used by hospitals without too much effort. I mean we had to buy all the devices to get them running inside the hospitals. Of course, the more you get into it, the more requests come up from clinicians because, then basically, you need to put up a COVID-positive, as we call it, patients and a non-COVID patients ICU.

There are really two different ICUs for different kinds of patients. Hopefully, once this empties, the COVIDpositive, while the other doesn't, but then everything is doubled up. So, you need two more ultrasound machines, more point-of-care diagnostics, and many other devices. For example, the emergency ward requires for extra ultrasound machine to do first screening of the patient's, portable x-rays because they're easy to handle. They give you a good shot at the beginning, and then, they're really easier to assess rather than CT scans.

ITALY: WHAT SUPPLIES ARE RUNNING OUT

Umberto Nocco: One of the problems we are starting to face right now, and we are talking about right now and in the past two or three days, is the problem about spare parts. I don't have data on this, but one thing I must say is that probably ventilators run more steadily, if you see what I mean, because they're running on the same patient for a long time, so they suffer less failure if compared with the time when you have a higher patient turnover in the ICUs. So basically, technology is more stable, but then you need a lot more oxygen cells because they fail more often, probably it is due to the higher oxygen concentration used.

And also one of the other problems is the consumption of oxygen. I don't have calculations handy, but lump figures say that we kind of doubled up, or maybe more than that, the oxygen used in the hospital. And so you need to increase the capability of the tanks, of the oxygen tanks. And also you need to be sure that you give an extra boost to the oxygen in the flow because continuous pressure airways support system use very high flows. And when you have many of them connected to the same pipe, you might end up figuring out that you're not really giving the patient the wanted flow of oxygen because everybody's sucking up from the same reservoir. So basically that's what it is.

ITALY: TACKLING ORGANIZATIONAL ISSUES

Umberto Nocco: At the beginning of the outbreak we had to divide production lines, especially in the ERs, sorry for my poor English, and I hope you understand what I mean. Basically you need to define which wards and which ICUs, if you have them, you want to put positive patients in and which wards you want to put non-positive patients in.

I know it's a stupid point of view, but the thing is that normal patients will show up anyway. So if you have a contagious disease ward, which is usually designed also with regard to air flux and isolation of the rooms, then you're quite ahead. But at least in Italy, those are really a few and usually they don't have so many beds as needed in this kind of an outbreak. So you need to use a general ward, which is usually not designed to handle this kind of situation.

You need to set it up with monitors, continuous pressure airway support system, point of care diagnostics, personnel, which we're really running short of personnel, and protection devices. These can be set up in advance. Of course, if you know where to put patients, where you're really staying there.

And this process division has to, at least we experienced, you have to figure it out also in the emergency ward, especially if you need to have basis for clean patients because unfortunately, as I said before, strokes, trauma still happen. Although we experienced a significant decrease, especially after lockdown, it seems like patients don't have strokes anymore. We're kind of asking, "Why?" But there are fewer cases that have come up to the hospital, luckily.

Of course, you have to have completely different spaces for known or suspect positive patients and known positive patients. This basically is like having two emergency departments inside the same hospital. Also from an asset point of view, so you need to have the space, and you need to have the technology to make it run.

Another thing is about biomeds and biomedical equipment technicians and as hospital technology management people who kind of walk around the hospital just to have everything set. We need to be alert. Of course, this is easy to say, but it's hard to handle. But one thing is that you may need to define where to go and especially when it's worth or needed. By this, what I mean, this is mainly to prevent exposure to the virus, to the biomeds, and to your people in your organization, plus, to reduce the use of the protection clothing and devices, which are always short.

And so this might not be liked by the personnel, at least it is not liked in Italy, they don't like to attach cables, but sometimes some really easy basic line maintenance probably should be given out by nurses and people who can do that inside the ward without biomeds and people from the health technology department going inside a kind of positive area, which has all kind of problems.

ITALY: THE CHALLENGE OF ACQUIRING DEVICES

Umberto Nocco: Last, but it's still a major problem, probably it's more local because it's probably it's more related to the way we acquire devices in Italy. I won't get into the details related to public tenders, which probably don't apply to the U.S. market, but to some extent we faced a kind of saturation of the capability to produce devices, which is probably typical of medical device market, which is not usually accustomed to producing by the hour in great numbers, if you see what I mean.

So, we were the first, and so we were able to use stocks, and we were able to acquire some numbers of devices at the beginning of the outbreak. But after a short time, we started experiencing a longer and longer time to hospital, as they call it, for ordered goods. Orders given today are scheduled to be given to the hospital by the mid of April. So that's way too long. We need the devices before that. And we also experience lower quality due to a certain, probably to the speed on the production line, details that are not present on the devices, things that are missing, things that probably are not assembled very well and stuff like that.

Last thing, is how many devices do I need? Basically, it's another way of putting the question I started with. We had hospitals where more was never enough, still today, and hospitals where you had the feeling that you were doing something wrong in acquiring all that kind of technology because it didn't seem like needing more devices and beds and somebody else might have a need rather than you.

The problem is that you never know. You never know what's going on tomorrow. Also, all these nice curves of patients that we see every day, we're not really sure they're correct. So we don't know what will be happening in the hospital tomorrow, how many cases we have at home, and they're are not even aware that they have COVID-19, and they might end up in a hospital in a couple of days. So it's really hard to find the balance when you have to decide how many devices, which type, what you want them to do, and how you want the thing run.