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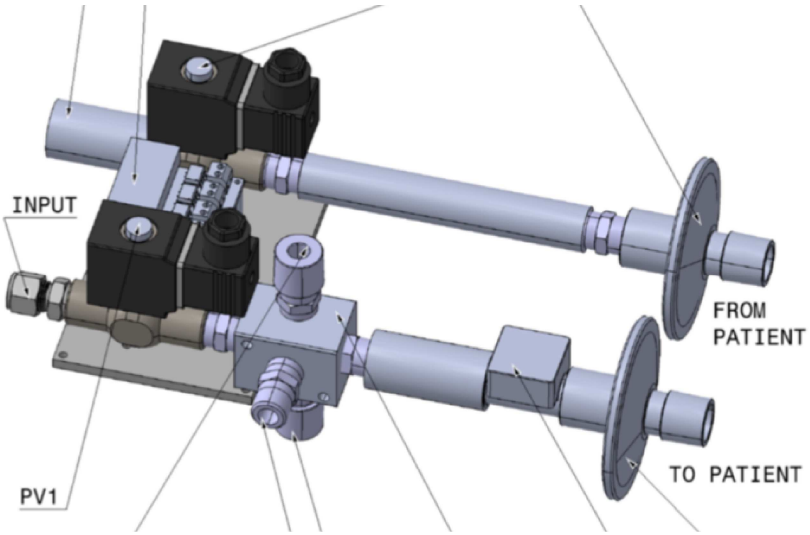

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When Italy went into lockdown, scientists from all over the world came together as friends to fight COVID-19

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"It was very relieving, personally, to see so many friends in the U.S. and Canada, and in Spain, and in France, and in the U.K., and Poland, come to our aid," said Cristiano Galbiati, one of over 100 scientists teaming up to design the MVM ventilator.

MVM

The first confirmed case of COVID-19 disease in Italy appeared on February 20th, in the administrative district of Lombardy, which includes the city of Milan. The next day, in the neighboring district of Veneto, in the town of Vo', near Padua, the first death from the disease in Italy was recorded.

Italy went into lockdown March 9th. The sudden, drastic measures woke up the world to the deeper risk of COVID-19.

For Italians, there was another shock, a feeling of isolation.

"For many weeks in Italy, we were at the center of the epidemic, and it felt really bad because it looked like it was a problem limited to Italy," recalls Cristiano Galbiati, a physicist in Milan.

"We felt at times that other nations in the European Union really were not appreciating what was happening here."

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Then he did something that showed Galbiati that Italy was not, in fact, alone. He came up with an idea for a novel kind of mechanical ventilator. It would be cheap and easy to build. Ventilators were in short supply, so this had a real chance to help save lives. He called scientific colleagues all around the world to enlist their aid. They heeded his call by the dozens. Before long, there were over a hundred scientists on Zoom calls, multiple times a day, coordinating the science, the prototyping, the testing, and the construction.

This month, the effort, called The Mechanical Ventilator Milano, reached a major milestone. The U.S. Food & Drug Administration granted an "emergency use authorization" to the device.

In a phone call from Italy, Galbiati recalled how it all came together, obviously moved by the show of support.

"It was very relieving, personally, to see so many friends in the U.S. and Canada, and in Spain, and in France, and in the U.K., and Poland, come to our aid," said Galbiati.

"It's been a great international teamwork exercise," said Art McDonald, a recipient of the 2015 Nobel Prize in physics, and a longtime collaborator of Galbiati's, who serves as a co-leader of the project. "It's been heartwarming to see just how pleased these people are to be able to do something to contribute to dealing with the COVID-19 crisis."

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ZDNet described the MVM project in April, based on the initial paper posted by the group on March 27th on the

medRxiv pre-print server. (The paper has since been updated. The project website has additional information.)

Galbiati spoke to *ZDNet* by phone from Milan on May 8th to offer an update on the group's progress.

Things are brightening in Italy as the daily number of cases has declined, though Galbiati can't yet return to his laboratory.

"There is a little beam of hope," he said. "People were finally able to poke their noses out of their homes and the mood is lighter."

Getting to this point meant working at "warp speed," as McDonald puts it. For Galbiati, it first required moving past the feeling of being frozen.

"The first week was a week of utter disbelief and shock," he said.

"For a few days, I felt I could not function."

Ordinarily, Galbiati and colleagues would be focusing on their current project, a mile below the Gran Sasso mountain range in central Italy. Galbiati is a professor in the physics department at Princeton University, but also holds a teaching appointment at the Gran Sasso Science Institute.

Called the Global Argon Dark Matter Collaboration, formed in 2017, the collective of scientists has been for the past couple of years building a dark matter detector called the "DarkSide-20k" in a tunnel underneath Gran Sasso. Shielded from the radioactive particles that bombard the earth's surface, the detector is finely tuned with a network of compressed argon gas to pick up the very faint traces of dark matter. (More information on the DarkSide website.)

Ordinarily, Galbiati and colleagues would be focusing on their current project, a mile below the Gran Sasso mountain range in central Italy, a dark matter detector called the “DarkSide-20k,” consisting of a cryostat inside a spherical stainless-steel scintillator 26 feet in diameter suspended inside a fifty-by-fifty-foot water tank.

DarkSide-20k

Under lockdown, Galbiati and his Italian collaborators couldn’t get into the facility. “My mind at that moment in time was really changing,” he said, “in the sense that I felt it was much more important to do something about this this situation than to go on with our regular research.”

On March 19th, Galbiati was talking in Milan with a collaborator from his dark matter work. “I told him we ought to be able to do something” about the pandemic, Galbiati recalled.

His mind turned to the highly complex instruments he had spent years building. The most challenging work of Galbiati’s career is a massive

instrument called Borexino, also built at Gran Sasso. Galbiati described that detector as “two very delicate hyper lungs,” enormous containers formed of a super-thin sheet of nylon, measuring just 125 millionths of a meter thick. “You needed to treat it very, very gently,” he recalls of the process of moving argon gas through the giant lungs.

A human lung is “a very complicated, an extremely delicate organ,” Galbiati reflected. Nevertheless, “if you look at it, at the end of the day, it boils down to basic physics.” Lungs can be defined by a minimal number of physical parameters, he reflected: “The resistance of the air pathway and the elasticity, also called the compliance.”http://www.zdnet.com/”

“The performance of any ventilator is in essence defined by its ability to work within the complete allowable range of parameters while guaranteeing very smooth transients for the pressure and volume waveforms,” explained Galbiati.

That day in March, Galbiati didn’t sketch his concept on a cocktail napkin. “A napkin of mine would be something that would be unintelligible to other people,” he said. Instead, he reached out to colleagues who would quickly understand his vision.

“I’m very lucky that I have a set of collaborators that I work very well with in my dark matter experiments,” said Galbiati. “The way we do it is, I call up the three, four guys that I know to be most close to my way of thinking.”

Chief among those were Cary Kendziora, an engineer with the Department of Energy’s Fermilab in Batavia, Illinois, and Hanguo Wang, a professor of physics at UCLA, two “mechanical gurus,” as he calls them. Galbiati called Kendziora and Wang on March 21st, two days after his original inspiration, “and by the end of the night, we had a beautiful illustration that everyone could understand.”

A schematic of the main system of valves and sensors in the MVM.

Galbiati et. al 2020

For the control unit of the ventilator, the electronic brains, including the processor chip and software, Galbiati reached out to another longtime associate, Alessandro Razeto at Gran Sasso. “I just explained to him in a couple of words what we needed as a control unit, and six hours later, he had that concept completely fleshed out,” said Galbiati.

Galbiati phoned McDonald, the Nobel Prize winner, to enlist his support. “I immediately saw it was a good idea,” said McDonald. “But I also recognized that it would be valuable if we could broaden the effort.”

McDonald rallied his colleagues at various Canadian institutions, including The McDonald Institute at Queen’s University in Kingston, Ontario, from which McDonald has retired but where he still maintains an affiliation; TRIUMF, the Canadian national lab for

particle and nuclear physics, in Vancouver; Canadian Nuclear Laboratories, Chalk River; and SNOLAB, another dark matter laboratory, buried underground near Sudbury, Ontario.

Galbiati also tapped Fernando Ferroni, president of the Grann Sasso Institute, to be a co-leader of the team along with McDonald.

Many years of collaboration made it so the organizational structure of the project just about fell into place on its own. “The organization structure is pretty similar to the structure that you have for a major project,” said McDonald. “Cristiano and I have been working together for quite a while and it wasn’t hard for us to agree on what the major task areas were that we required, and then we were fairly quickly into the project able to identify people who were skilled in those areas and also people within the areas that were showing leadership.”

Remarkably, what ended up in the research paper that Galbiati and colleagues posted on March 23rd was more or less what Galbiati initially imagined, albeit with refinements.

There was fine-tuning of the design that happened with the help of Italian doctors whom Galbiati traveled to see.

“Cristiano himself is an amazing individual,” said McDonald. “He has been dealing with a very difficult situation in Italy.”

“He had to get a special dispensation from the government simply to travel within the Milan area.”

The first physician to weigh in was Antonio Besenti, who runs the crisis unit in Lombardy, which was inundated with cases in the first weeks of the outbreak.

“He was very inspirational to me,” said Galbiati of Besenti. “He gave

me directions on how the lungs should be treated with kindness and a very gentle action." Besenti directed Galbiati to work with his protégés, Drs. Giuseppe Foti and Giacomo Bellani of the Hospital San Gerardo in Monza, near Milan; both physicians share authorship on the MVM paper. Foti and Bellani helped Galbiati refine his understanding of the physics of the lung.

"For COVID-19 patients, it is extremely important that the peak flow delivered at the beginning of the breathing cycle be very high, in order to fill up immediately the alveoli, all while maintaining a very smooth pressure waveform," explained Galbiati.

To make sure things are proceeding correctly, doctors have to check patients on a ventilator four to five times daily. Each such check involves pressing five or six different buttons on the control panel of a ventilator. On the advice of Foti and Bellani, the MVM team simplified the matter drastically. Doctors and nurses will be able to perform the same procedure with a single press of a button on the MVM's control panel, said Galbiati.

The complete MVM ventilator, from product literature of Vexos, one of three firms mass-producing the device.

Vexos

"I don't think it's any less daunting than what we're trying to do in our experiments," said McDonald, comparing the work to the search for dark matter. "We are always very careful from a safety point of view, but in this case, we're dealing with human lives."

"That's a daunting prospect when it comes to what you're designing and how careful you have to be."

Ventilators have not been without controversy. Some physicians have suggested that more needs to be done to

avoid ventilator use in general, because they can have long-term deleterious effects on patients.

How serious are the concerns? "I'm not a doctor, so I think that decision would be left to them," Galbiati told *ZDNet*. "What doctors tell me is that it is a measure of last resort, and unfortunately it's a measure of last resort that has to be adopted for a very significant fraction of patients."

Asked by *ZDNet* whether the MVM ventilator might be safer than some commercial ventilators because of the way it is designed, Galbiati again deferred to physicians.

"I believe these questions will need to be addressed by medical doctors in clinical studies," he said.

In addition to the FDA's emergency-use approval, Galbiati and team have applied for an emergency-use grant in Italy from the Italian Ministry of Health. The MVM is the first device ever to apply for such authorization in Italy in the 23 years that the emergency-use law has been in place, said Galbiati.

Galbiati and the team have also begun the application for permanent FDA approval, and also for permanent approval under what's called "CE mark," the over-arching authorization in the European Union.

Mass production of the MVM is underway at Elemaster S.p.A., a manufacturing services firm based in Italy Galbiati and colleagues have relied on for years for their work; and in the US and Canada at the facilities of manufacturing firm Vexos, with additional production in Canada by JMP Solutions of London, Ontario.

The initial target for production by Elemaster and Vexus and JMP is hundreds of units per week. As the production process becomes more

and more streamlined, Galbiati expects the rate can "rise significantly in the months to come."

"If you look at the simplicity of the machine, it's astounding," said Galbiati. "It's something that is very, very easy to assemble and requires remarkably low manpower." Among the most important design points was the use of a what's known as a manifold, a single piece of metal that serves to join multiple parts, such as valves.

"All the engineering in order to integrate the machine came out quite naturally from past experiences at building other stuff," said Galbiati.

The MVM design is open, meaning the scientists are not patenting any intellectual property, McDonald noted. That means that other manufactures could conceivably grab hold of the design and enter the market.

"That is our humanitarian contribution, if you like," said McDonald. "We're being very open, as scientists generally are; it's a good example of how international cooperation and science can be helpful."

The collaboration for Galbiati is a vindication of the fundamental value of basic research. "People are very curious in this field, and they are able to recognize something that is important," said Galbiati. "When the moment comes, you can steal a lot of talent towards something that is recognized immediately of great use to society."

The fact that so many jumped aboard, "tells you how nimble is this work of basic research."

The other basic research, the work underground at Gran Sasso, the hunt for dark matter, will have to wait. Galbiati is not sure when he'll be able to get back into the lab. He's adapted to a change in habits, he said, and he has embraced a requirement for patience. "Everything in life has its own right time," he said.

Galbiati is more focused on changes yet to come, in particular, the possibility of a second wave of COVID-19.

“I fear most what’s going to happen in the fall,” said Galbiati.

“The much-warmer weather that we have here, starting in May, may play a role in dampening it down, but who knows what happens when the weather cools down again.”

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