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The Journal

VOLUME 20 • ISSUE 3 • 2020 • € 22

ISSN = 1377-7629

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### CoviLake Niguarda: Trying to Predict **COVID-19 Patient Path**

COVID-19 is a new and largely unknown disease, which makes it difficult for clinicians to make prognostic decisions. CoviLake Niguarda is a project aimed at creating Al algorithms and a decision support system (DSS) feeding from a datalake of all relevant patient information to support clinical decision-making on the front line.



Since the first COVID-19 outbreak in Wuhan, China, researchers are collecting data about the novel coronavirus to better understand its characteristics and behaviours and, eventually, to help in both treatment and prevention of COVID-19 in populations around the world. One such promising initiative, CoviLake Niguarda, is being launched in Italy as a collaboration between major hospital, academic and industry entities.

#### Problems and Goals

The CoviLake Niguarda project consists of activating and feeding a vendor neutral archive (VNA of Agfa HealthCare) and a datalake (of InterSystems) with anonymous images and clinical data related to COVID-19 cases within Ospedale Niguarda, the largest and one of the most important hospitals in Milan, Italy.

Currently, 80% of the 1,000-bed Niguarda is allocated to treat COVID-19 patients, as are most of its staff. COVID-19 is a complex disease, and detailed information about the virus and its mechanics is still unknown. This adds to the burden of clinicians on the front line. The clinical problem with the COVID-19 patients is the very broad spectrum of manifestations, from mild flu-like symptoms to pneumonia and respiratory distress. The ultimate goal of the CoviLake Niguarda project is to try to predict the possible scenarios of the disease development in each patient and to support the prognostic decision-making for radiologists, emergency department physicians, anaesthesiologists, infectologists, and other specialists.

In particular, the clinical goals are:

- 1) Prognostic prediction: Identification of (bio) markers to predict prognosis and stratify patients based on disease severity.
- 2) Therapeutic forecast: Identification of (bio) markers to predict the most appropriate therapeutic intervention.
- 3) Active monitoring (during hospitalisation): Identification of (bio)markers to classify individual susceptibility linked to evolution to severe forms.
- 4) Active monitoring (at discharge): Identification of (bio)markers to identify residual frailty situations that need further monitoring.
- 5) Differential diagnosis of active/residual disease: Categoriser to distinguish active/residual COVID19 manifestations from similar pathologies.

#### Data Acquisition and Methodology

Thanks to the voluntary contribution of Agfa Health-Care, InterSystems, Medas, Sazai, QUIBIM and Nextage, it was possible, in a very short time, to design a stateof-the-art computer system to support clinical-scientific research aimed at diagnosis and treatment

through a large interdisciplinary group that includes radiologists, physicists, anaesthesiologists, infectologists, pharmacologists, and emergency department physicians, among others.

At this stage, the team is working to create a solid foundation for the project focusing on the quality of data to be used to train the artificial intelligence (AI) system, and the methodology behind it. While collecting data is a relatively simple task, putting together and connecting the clinical and imaging data is a novel approach, for which the datalake format has been chosen. Datalake is an 'open container' filled with relevant information from different sources, such as images, CT scans, ultrasound, x-ray, blood tests, etc anonymised and properly labelled.

Notably, Niguarda, with two other major facilities in Italy, was one of the first hospitals in the country to be digitalised. It partnered with Agfa Health-Care back in 2001, and since then all their data are stored online, which now makes over 250 Tb of patient history only in radiological data. For the CoviLake Niguarda, this makes it possible to have both retrospective and prospective assessments of a patient. In other words, current observations and predictions can be complemented with the data from years ago, if needed. Whether the patient had been in the hospital before, what their treatment was, whether there are any underlying conditions - all this information can be extracted, added to the datalake and used to support the decision-making process and, as the pandemic develops, to follow the patient's quality of life post-COVID-19.

Rigorous anonymisation of the clinical data and images has been another important topic that the group has had to address. The solution adopted has found the consent of the Niguarda Ethics Committee to allow the ongoing study. It enables application of high-level competencies that are not specifically connected to the GDPR profile and opens the data up to be used by other research groups.

#### **Technological Aspects**

The clinical documents and the archived images, correlated by the datalake, will be the subject of analysis and study by the University of Milan and the QUIBIM company of Valencia that, with the support of clinicians, will try to create AI algorithms and a decision support system (DSS) to help better understand the mechanisms by which the COVID-19 virus acts/ evolves. This is expected to provide clinicians with greater insight into a patient's potential reaction to the infection and the degree of support they might require.

The technology part of the CoviLake Niguarda project includes:

- · The acquisition, through special integration of images and clinical documents of COVID-19 patients being studied, from the PACS and Niguarda Repositories systems.
- · Anonymisation, through specifically designed computer modules, of images and clinical data.
- · Submission to the VNA and the datalake of anonymised images and anonymised clinical data respectively.
- · Installation and configuration in a functional way to the project of the VNA and the datalake, and tools for the correlation between clinical data and images.
- The study, analysis and implementation of Al algorithms and a DSS system, using images and data present in the VNA and the datalake, and aimed at giving answers to the project clinical questions.

#### **Project Coordinators**

Dr Marco Bosio, CEO of the ASST Great Hospital Niguarda, drives a large 'teaching hospital' with multidisciplinary skills oriented to patient care. Under his leadership, professionals from different disciplines work together to address the challenges of these years, including the COVID-19 pandemic.

Dr Angelo Vanzulli, Director of the Department of Advanced Technologies and Professor of Radiology at the University of Milan, will coordinate the clinicalscientific research that will be carried out by a team of multidisciplinary doctors including radiologists, anaesthesiologists-resuscitators, pneumologists and virologists.

Dr Alberto Torresin, Director of Medical Physics of Niguarda, Professor in the Department of Physics of the State University of Milan, is responsible for the technical aspects of the CoviLake Niguarda, while Dr Maurizio Menni of Sazai, an innovative start-up in Milan that deals with AI in the medical field, cooperates with the technology partners.

#### Timeline and Plans

In the next 2-3 months the group is planning to feed into the datalake all the available data for nearly 1,000 patients. 10% of those will be used at the initial stage to train the AI system, and the rest to test and adjust its ability to predict the development of COVID-19 in patients. It is expected that in about six months the project will deliver preliminary results with the Al system set up and will have the ability to analyse the data. Additional evaluations might follow, if necessary.

For the time being the research is focused on COVID-19, since it is a new and unknown disease. It is too early to say if its results can be applied to other diseases, but the methodological approach may be of interest for future studies of other kinds of pathologies with similar clinical questions.

Furthermore, there are aspirations to expand the datalake to the regional level with the support from Agfa HealthCare and other companies. Currently, the project is at an early stage and has been authorised to run only in Niguarda, but cooperation with other hospitals in the region is a future option, which is being looked into. ■

#### ■Interviewee: Prof. Angelo Vanzulli

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