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Lean-ing Method in an Emergency Department of the Italian Epicenter of the COVID-19 Outbreak: When the Algorithm Makes Difference

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Abstract: The Lean method entails a set of standardized processes intending to optimize resources, reduce waste, and improve results. Lean has been proposed as an operative model for the COVID-19 outbreak. Herein, we summarized data resulted from the Lean model adoption in an Emergency Department of the Lombardy region, the Italian epicenter of the pandemic, to critically appraise its effectiveness and feasibility. The Lean algorithm was applied in the Humanitas Clinical and Research Hospital, Milan, north of Italy. At admission, patients underwent outdoor pre-triage for fever, respiratory, and gastrointestinal symptoms, with a focus on SpO₂. Based on these data, they were directed to the most appropriate area for the COVID-19 first-level screening. High-risk patients were assisted by trained staff for second-level screening and planning of treatment. Out of 7.778 patients, 21.9% were suspected of SARS-CoV-2 infection. Mortality was 21.9% and the infection rate in health workers was 4.8%. The lean model has proved to be effective in optimizing the overall management of COVID-19 patients in an emergency setting. It allowed for screening of a large volume of patients, while also limiting the health workers' infection rate. Further studies are necessary to validate the suggested approach.

Keywords: COVID-19; emergency department; lean; management algorithm; SARS-CoV-2

1. Introduction

The Coronavirus Disease 2019 (COVID-19) outbreak, with its unprecedented impact on the global health system worldwide, forced healthcare providers into searching for solutions. Northern Italy, particularly the Lombardy region, was the epicenter of the pandemic, and the more and more widespread Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection imposed the vital need for logistic and organizational rearrangements within hospitals, unprepared to face the health emergency.

The healthcare system and internal hospital organization had to solve at least four problems, namely, counteract the contagion in the population, offer the best medical and intensive treatment to the infected patients, limit the infection rate among the health workers, and keep the level of care for other pathologies adequate. The compulsive search of the most suitable model to meet these four main requirements led to hypothesizing a theoretical advantage of the Lean method.

Lean philosophy has been widely diffused in healthcare in order to reduce waste, improve the quality of care and efficiency, and to ensure patient safety.

A recent work systematically reviewed a lean management application in the Emergency Department, highlighting the multiple benefits of its adoption reported in the



Citation: Desai, A.; Goretti, G.; Giordano, M.; Voza, A. Lean-ing Method in an Emergency Department of the Italian Epicenter of the COVID-19 Outbreak: When the Algorithm Makes Difference. *Appl. Syst. Innov.* 2021, *4*, 55. https:// doi.org/10.3390/asi4030055

Academic Editor: Zeeshan Asim

Received: 7 June 2021 Accepted: 6 August 2021 Published: 12 August 2021

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Copyright: © 2021 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). literature [1,2]. Particularly, lean helps to overcome various challenges such as waiting time, patient flow, bed unavailability, difficulty in screening, and length of hospital stay. The study also revealed the importance of the interaction between working groups, which is imperative for lean implementation. The leaders' commitment to teamwork progress and the continuous improvement culture are essential elements too. Chen and colleagues reported lean adoption to establish a fever of unknown origin (FUO) emergency department combining daily operation with prevention and control, helping China and other countries to handle the outbreak of fulminant infectious diseases, through the implantation of information technology, the local transformation of the site, the rational allocation of medical teams, and the planned distribution of protective equipment, in a short period of time [3]. Additionally, other studies focused on the emergency pathway in the COVID 19 period. Patey and colleagues reported a re-organization in a rural emergency department during the coronavirus disease 2019 (COVID-19), although without using lean principles [4,5].

The inspiring principles of the Lean operative model make it an ideal candidate for the management of a COVID-19 outbreak within the emergency department (ED), compared to standard treatment algorithms that do not provide detailed and specific paths for SARS-CoV-2 patients. The Lean method is concretely realized by gradual and standardized steps, now identifiable by the term "Lean-ing" [5–7].

The present short communication is aimed at a critical appraisal of the overall results of what we started to refer to as "Lean-ing" in the management of COVID-19 in our ED.

The efficacy of the adoption of the Lean model in limiting the contagion among health workers was also analyzed.

2. Materials and Methods

2.1. Humanitas Clinical and Research Hospital Emergency Department

The Humanitas Clinical and Research Hospital (HCRC) is based in Milan, the Lombardy region, north of Italy. It is a scientific institute for research, hospitalization, and health care, as well as a worldwide reference for research on diseases related to the immune system. HCRC is a private hospital, which also serves a public service by way of a contract agreement with the Lombardy region. It involves 747 beds, 43 operating rooms, 200 examination rooms, and more than 3000 professionals, accounting for 45,000 new admissions/year from Italy and abroad. The ED was built taking into account the most advanced models of construction and organization to ensure optimal patient management and started operating in November 2003. It has a separate entrance from the main hospital block, a Shock Room for emergency management with priority, 7 examination rooms, and 14 observation stations. A team of Internists and Emergency Surgeons is constantly present (24 h a day). The turnover of the ED consists of 55,000 patients/year.

2.2. The Lean Operational Algorithm

Lean healthcare is a "tools-based approach". The algorithm is built on lean tools and techniques implementation [8].

The Lean model applied for the management of the SARS-CoV-2 pandemic outbreak encompassed the implementation of standard work, with the aim of optimizing clinical practice and being able to implement the quality of care. Everyone has to follow the standard work to grant the highest quality of treatment for both the patients and the hospital until a more appropriate approach is found. In that case, it becomes the new standard of care.

Firstly, a pre-triage internal protocol was defined (Standard work). Patients were screened outdoors for fever, respiratory, and gastrointestinal symptoms to determine the most appropriate route to take in ED. Patients with SARS-CoV-2 symptoms were directly transported to the COVID-19 Hospital facility hospital, where they underwent our first-level screening in a designated isolation area. A well-trained, fully personal protective equipment (PPE)-dressed nurse conducted the nasopharyngeal swab, pulse oximetry, took vital signs, and performed a rapid physical examination. Suspected cases were triaged

in a specific isolated area to assign an appropriate priority code. Particular attention was paid to peripheral oxygen saturation (SpO₂%): Patients with a SpO₂ < 90% (or < 86% if chronic obstructive pulmonary disease—COPD patients) were immediately assigned a code 1 or 2 and placed in a high-intensity treatment area; subjects with a SpO₂ > 94% were assigned a code 3 or higher and placed in a less-intensive treatment area. The gray zone was represented by suspected patients showing a 90% < SpO₂ < 94% (ore 86% < SpO₂ < 90% if COPD). Those patients were administered low-flow oxygen (4liter/min) with a nasal cannula in order to evaluate any improvement in SpO₂. Patients with no or poor improvement in peripheral oxygenation were assigned with a code 1 or 2 and placed in the above-mentioned isolated area. Furthermore, all patients received a prompt full medical evaluation, chest ultrasound (US), laboratory blood tests, and supplementary oxygen and medical treatment if required (Figure 1).

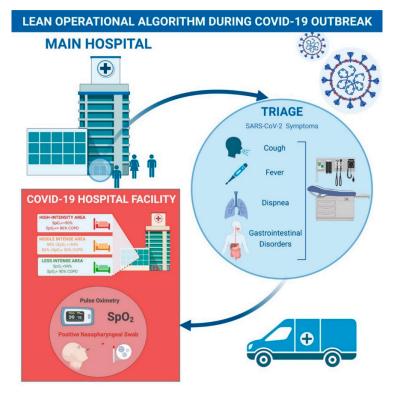


Figure 1. Lean operational algorithm used during the COVID-19 outbreak.

In the emergency setting, where time is vital and the rate of patient inflow is high, the risk of potentially making a mistake is greater. In the Lean methodology, human error can lead to a process failure. Based on this assumption, lean adopts simple tools to decrease the error rate (Poka Yoke). Inside the isolation area, a whiteboard was placed for the visual check (visual management) of all patients in order to always have the necessary information for the correct management of the patients available (Figure 2). Additionally, symbols were drawn on the floor to make the paths to follow clear and reduce the possibility of infection as well as logistical errors. In addition, hospital statistics and data reports were created and reviewed daily to improve the standards of care.



Figure 2. Whiteboard visual check.

Lean has two primary goals, namely the identification and elimination of inefficient processes (i.e., waste elimination such as waiting, movement, overprocessing), and the integration of co-workers' feedback (multidisciplinarity and engagement). Of great importance was the feeling of being part of a united group. Health workers were involved in all levels without neglecting anyone's opinion. Weekly multidisciplinary meetings were held to share and improve logistics, clinical, and relational management leading to a constant increase in efficiency and safety. Figure 3 summarizes the Lean approach to COVID-19 in the ED.

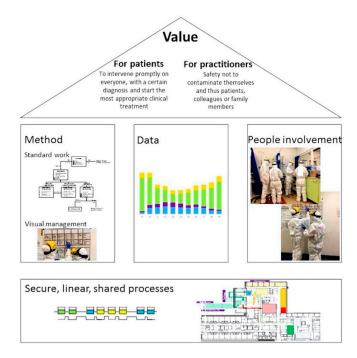


Figure 3. Lean approach to COVID-19 pandemic in the Emergency Department.

The overall data of patients managed at the ED in the timeframe February 21–May 28 2020 have been retrospectively analyzed.

3. System Operational Results

A total of 7778 patients were admitted to the ED, of which 1709 (21.9%) were suspected of SARS-CoV-2 infection. The average number of daily access and daily cases suspected for COVID-19 were 79.36 (\pm 23) and 17.4 (\pm 8), respectively. Among the suspected cases, 133 patients (7.7%) were assigned with a code 1420 (24.5%) with a code 2, and 1156 (67.6%)

with a lower priority code. After clinical, instrumental, and laboratory evaluations, a total of 820 patients (47.9% of the suspected cases) met the WHO interim guidance criteria for the SARS-CoV-2 diagnosis. One hundred and eighty patients died, accounting for an overall mortality of 21.9%. All the patients were managed based upon the best standards of care. One hundred and seventy (4.8%) professionals tested positive for SARS-CoV-2.

4. Discussion

In December 2019, the novel coronavirus emerged in Wuhan, the capital city of Hubei, China. The enveloped RNA betacoronavirus has been soon named SARS-CoV-2 due to its phylogenetic similarity to SARS-CoV [9–12]. On February 20, 2020, the first case of the novel COVID-19 was detected in Italy, and 20 days later, WHO declared the COVID-19 outbreak a global pandemic [13–16]. Italy had one of the highest rates of SARS-CoV-2 infection worldwide, with 3044 cases per 100,000 people, as well as the second-highest mortality rate, 13.4% vs. an average value of 6.9% (as of 22 April 2020; https://coronavirus.jhu.edu/map.html (accessed on 13th February 2020)). The Lombardy region, with 10.6 million people living in highly populated areas, has been the epicenter of the infection, with 37.4% of total cases registered in the country and more than 50% of the total number of deaths (http://www.salute.gov.it (accessed on 13th February 2020)) [17–19]. The disarming rate of mortality was not only related to severe pneumonia but also highly influenced by the COVID-19 multiorgan involvement [20]. Comorbidities, cardiovascular complications, renal or liver failure, hyperinflammatory response, acute shock, and neurological sequelae are to be considered as the most insidious and unpredictable aspect of the pandemic [21–38].

The overall condition of the north of Italy was further worsened by the unpreparedness of the health system, as in most of the world. This tragic scenario imposed the need to put in practice a management algorithm able to counteract the spreading of the infection, concurrently fighting against the time. In light of these assumptions and as for other diseases in the field of emergency medicine, a practiced, feasible, fast, and effective organizational model was urgently need, especially in the ED [39–48].

At the ED of the Humanitas Clinical and Research Center, we applied, soon after the declaration of the pandemic, the Lean model. As evidenced by the literature, the implementation of Lean offers tremendous opportunities in the ED to improve the overcrowding, costs, and time-wasting, compared to traditional models [49–55].

In 2009, Dickson and colleagues evaluated the application of the Lean method in the ED and demonstrated the decrease in length of hospital stay and increase in improvement of patient visits [56]. In 2011, Holden et al. overviewed the application of the Lean model in several American, Australian, and Canadian hospitals, revealing its organizational success [57]. Improta and his group, in November 2015, put in practice the Lean method in the ED of Cardarelli Hospital in Naples. Data acquired revealed the effectiveness of this strategy in cost containment and patient safety [58]. More recently, in 2021, Aminjarahi et al. performed a review about the application of Lean techniques in ED, also with the aim to improve the quality of treatment [59].

In accordance with literature results, applied to our ED, the Lean approach appears to reduce errors and waiting time leading to an improvement in the quality of care for the patients. It was defined for patients and health professionals, prioritizing the wellbeing of both and ensuring secure, linear, and shared processes. The proposed model had extremely positive impacts during the outbreak and stands out as one of the few studies on lean adoption in ED to face and re-organize patients' admissions during the COVID-19 outbreak. Additionally, this work contributes to promoting an algorithm in which lean is integrated using a multidisciplinary approach [2].

Limitations

There are limitations of the present study due to its retrospective nature, the relatively limited number of patients analyzed, and the lack of randomization. Moreover, the main limitation is the extraordinary situation surrounding the world COVID-19 pandemic.

5. Conclusions

In our experience, the implementation of the Lean model has proved to be effective in optimizing the overall management of suspected or certain cases of COVID-19 patients in an emergency setting. It allowed one to screen a large volume of patients and to succeed them through valid priority codes. It has also been of value in limiting the health workers' infection rate.

While admitting the retrospective feature of our observations, as well as the relatively limited number of patients, the results of the present study present the experience of an ED in the Italian epicenter of the COVID-19 pandemic.

Future research will be directed to apply the Lean model to several health areas to build new protocols for clinical practice. The Lean strategy can improve the health system, even reducing costs.

Results of its practical application must be validated by further studies relative to the containment of the SARS-CoV-2 infection spreading and reduction of contagion.

Author Contributions: Conceptualization, A.D. and A.V.; methodology, A.D. and A.V.; validation, A.V.; formal analysis, A.D.; investigation, A.D. and G.G.; writing—original draft preparation, A.D.; writing—review and editing, A.V.; visualization, M.G.; supervision, A.V.; project administration, A.V. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: All data are included in the main text.

Conflicts of Interest: The authors declare no conflict of interest.

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