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Assessment of an organizational model during the first wave of COVID -19 in the South-Eastern Tuscany Health Unit: intensifying community services as prescribed by Ministerial Decree 77 of 2022

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Keywords: Covid-19; fatality; organizational model
Parole chiave: Covid-19; letalità; modello organizzativo

Abstract

Introduction. *At the end of 2019 a new virus, called SARS-CoV-2, emerged in Wuhan, China. The aim of the present study was to assess the impact of the first wave of the COVID-19 pandemic on the health system of the Tuscany Region and the response implemented by the South-Eastern Local Health Unit, also in view of the new reform of territorial healthcare established by Ministerial Decree Nº. 77 of 2022.*

Methods. *Data were taken from the "OpenToscana" database beginning when the first case was recorded in Italy (18 February 2020) until July 2020. We analyzed infections and deaths in each Local Heal.th Unit in the Tuscany Region and calculated the fatality rate (number of deaths/cases x 100) following COVID-19 infection. We subsequently compared the fatality rates among the Local Health Units by means of the Kruskal Wallis test.*

Results. *During the first wave, the South-Eastern Local Health Unit had fewer infections (a total of 1,532 by July) and fewer deaths (total: 107 by July) than the other Local Health Units. In the South-Eastern Local Health Unit, the fatality rate in July was 6.98%. The comparison of the fatality rates among the various LHUs and the whole Region showed statistically significant differences ($p<0.001$).*

Conclusions. *The organizational models promptly implemented by the South-Eastern Local Health Unit for good territorial care and the management of COVID-19-positive patients limited the spread of infection, and consequently the deaths, thus reducing the fatality rate in the first wave of the pandemic.*

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Introduction

In late 2019, a new beta-coronavirus was observed in Wuhan city, Hubei province, China. This virus, called SARS-CoV-2, caused a severe acute respiratory syndrome (1) and was mainly transmitted via droplets and aerosols (2, 3). SARS-CoV-2 infection may be asymptomatic or manifest itself through various symptoms, such as fever, cough, sore throat, weakness, fatigue and muscle pain; these symptoms vary according to the severity of the disease. More severe cases may present with pneumonia, acute respiratory distress syndrome and other complications, all of which are potentially fatal (3, 4). The risk of developing severe forms of the disease is higher in certain categories of people, such as subjects over 65 years of age, the obese, immunocompromised individuals, those with cancer and those with chronic diseases such as COPD, diabetes and heart failure (4, 5).

On the 31st January 2020, the Italian government declared a national emergency, in order to

tackle the incoming COVID-19 crisis (6). Restrictions were imposed on movements in and around the first affected cities, known as 'red zones' (7). Subsequently, movement restrictions were gradually implemented throughout the country, and on 4th March a nationwide closure of schools and universities was declared (8).

On 9th March, Special Continuity-of-Care Units (USCAs) were established in order to incorporate emergency health management of the COVID-19 epidemic into territorial healthcare (9). Each USCA was made up of a micro-team consisting of a doctor and a nurse, who could request advice from specialists when necessary (9).

On 11th March, a partial closure of bars, restaurants and leisure facilities nationwide was ordered, followed by their total closure on 22nd March (10, 11).

Phase 1 of the Italian emergency response ended on 3 May. This was followed by Phase 2 (from 4th May to 2nd June), during which most primary and secondary production sectors and most retail outlets, businesses and customer services resumed operations in accordance with sector-specific COVID-19 safety protocols (12). Previous restrictions on the free movement of citizens – i.e., only within their region of residence - were lifted. On 17th May, isolation measures were further relaxed at the national and local levels (13).

In this phase, a key role was played by the Italian Regions, which requested and obtained the right to establish specific regional guidelines (6, 14).

The SARS-CoV-2 epidemic affected the Italian Regions unevenly, with a north-south gradient being clearly discernible (6). While these regional differences were mainly due to multiple independent entries of the virus in northern Italy, they may also have been due to the different policies implemented at the regional level (6).

In the Tuscany Region, there are three Local Health Units (LHU: Azienda Sanitaria Locale, ASL in Italian); these are territorial branches of the Regional Health Service and guarantee the homogeneity of care in the various areas of the Region.

The "North-Western Tuscany LHU" (NW LHU) covers the cities of: Pontedera, Pontremoli, Portoferraio, Rosignano Marittimo, Seravezza, Vecchiano, Viareggio, Vicopisano and Volterra. The "Central Tuscany LHU" comprises Florence, Empoli, Prato and Pistoia. Finally, the

"South-Eastern Tuscany LHU" (SE LHU) covers Siena, Arezzo and Grosseto.

The surface area of the SE LHU is approximately 11,560 km², i.e. over half that of the entire Region, which is approximately 22,990 km². It is made up of 99 municipalities, 39 of which are mountainous, 20 partially mountainous and 1 insular. It has a population density of 70.36/km², i.e. less than half that of the Tuscany Region (159.36/km^2) (15).

The objective of our study was to assess the organizational model implemented by the SE LHU, evaluating the data from the first wave of COVID-19.

Materials and Methods

A retrospective observational study was conducted. The available population data came from the reports on COVID-19 published every day at 18:00 (UTC+1 h) by the Civil Protection Department, and were collected by ARS Toscana and processed by OpenToscana. These data are specific to the Tuscany Region and its three LHUs. Only aggregate data on infections and mortality were available, i.e. no information was provided on the age and gender of individuals. In addition, we gathered data on the number of SARS-CoV-2-positive cases, as ascertained by molecular swab, and on the number of deaths.

We then used these data to calculate the COVID-19 fatality rate (number of deaths/symptomatic diseased subjects x100). Finally, we compared the fatality rates of the three LHUs by means of the Kruskal Wallis test.

Our findings refer to the first pandemic wave, i.e. from the first confirmed case of COVID-19 in Italy to 31st July 2020.

Results

The first positive case in Tuscany was reported on 25th February 2020 by the CT LHU. The NW and SE LHUs recorded their first cases after 29th February. In total, from the date of the first case to July 2020, the CT LHU recorded 4,606 infections, the NW LHU 3,874 and the SE LHU 1,532.

The progressive total number of infections during the first wave is summarized in Figure 1.

The first death in the Tuscany Region occurred on 9th March in the NW LHU. In C LHU and SE LHU, the first deaths were reported on 14th March and on 16th March, respectively. In total, from the day of the first fatal event to July 2020, the C LHU had 550 deaths, the NW LHU had 469 and the SE LHU had 107.

The total progressive number of deaths during the first wave is summarized in Figure 2.

Using the total progressive numbers of positive cases and deaths, we calculated the total progressive fatality rate for each month and each LHU. The fatality rate in the C LHU peaked at 12% in June 2020 and remained stable in July 2020. In the NW LHU, the fatality rate peaked at 12.1% in July 2020, while in the SE LHU it reached a peak of 6.9% in June 2020 and remained stable until the end of the period.

The results are displayed in figure 3.

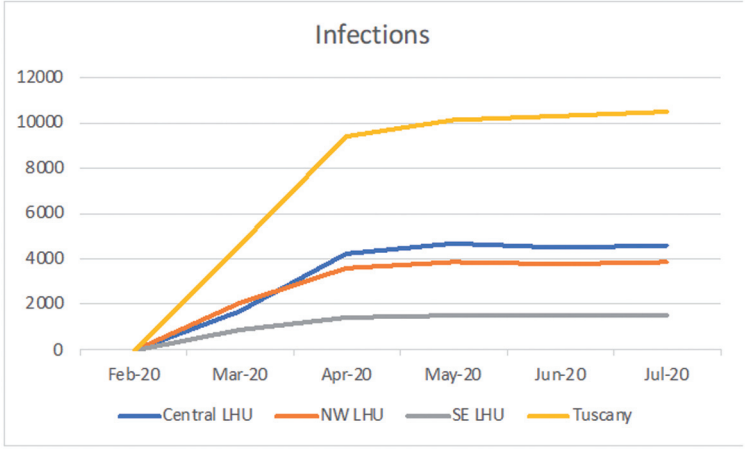

Figure 1 - Total progressive trend in infections

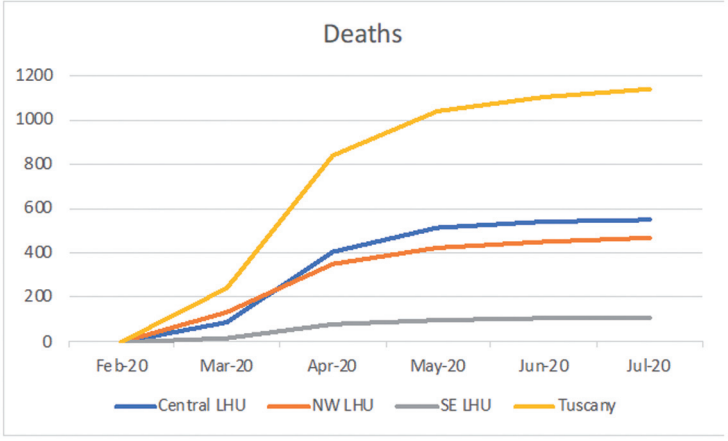

Figure 2 - Total progressive trend in deaths

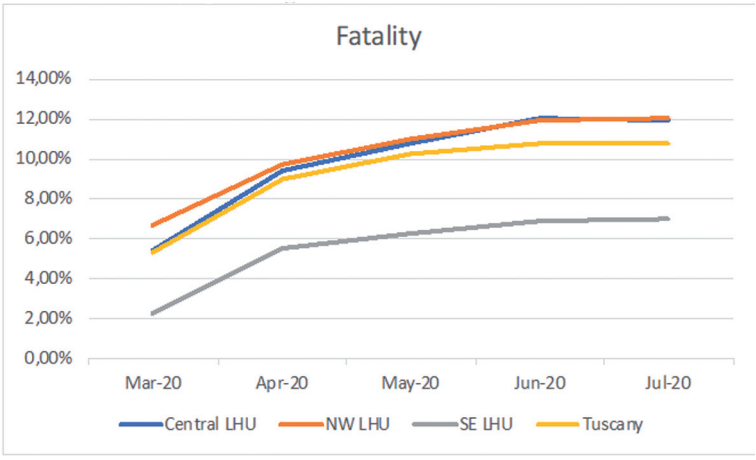

Figure 3 – Fatality rates in the first COVID-19 wave (March 2020-July 2020) SE LHU both with that seen in the other two LHUs and with the regional mean value, statistically significant differences emerged (*table 1*).

Table 1 - Comparison of fatality rates between the SE LHU and the Tuscany Region and other regional LHUs. Z: Statistical test; SE: Standard error.

Pair	Mean Rank difference	Z	SE	Critical value	p-value
SE LHU - TUSCANY	-86.388	32.955	262.139	691.593	<0.001
SE LHU – NW LHU	-1.263.571	48.202	262.139	691.593	<0.001
SE LHU – CENTRAL LHU	-993.458	37.898	262.139	691.593	<0.001

Reorganization of the SE LHU

The SE LHU implemented an extensive array of actions and strategies to deal with the spread of the pandemic. The first strategy involved the capillary activity of identifying cases through contact tracing and isolating these individuals and their contacts at home. A "COVID-19 Contact Tracing Center" was set up to cover the entire area of the SE LHU.

Community management of the cases was implemented through the rapid creation of 17 USCAs - teams composed of a trained physician and a nurse, who visited patients with moderate-to-severe disease in their homes.

Dedicated COVID-19 hospitals were also set up in Grosseto and Arezzo, where a total of 28 beds in special ICUs were reserved for COVID-19-positive patients. Moreover, 84 additional beds in ICUs could be made available within 48 hours, if needed. The same strategy was adopted in Infectious Disease departments: 118 beds were added and, in the event of a surge in hospitalizations, 192 more beds could be provided within 48 hours.

Hospital areas were reorganized and separated: specific "pathways" were created for COVID-19-positive patients in order to avoid cross-contamination among patients; 13 COVID-19 Short Intensive Observation (OBI) beds were created, and a specific area of each Emergency Department served as an intermediate level of hospital care between the ICU and inpatient admission.

In the emergency phase of the COVID-19 outbreak, the "Chronicity Center" assumed the role of COVID-19 Centre, with separate pathways being activated according to the patient's needs. The Center coordinated activities related to the management of non-hospitalized COVID-19-positive patients in close synergy with the hospitals; indeed, it activated the USCAs, arranged admission to "healthcare hotels" for positive individuals who could not be isolated from their relatives at home, and managed access to intermediate care and the use of nasopharyngeal swabs for the detection of SARS-CoV2.

In addition, a dedicated software, called GeCOV, was developed for the management of both positive patients and contacts. This software, which was used by the COVID-19 Center, the USCAs and the General Practitioners, allowed real-time visualization of the number of swab and serological tests performed, patient status and the planning of active surveillance (16).

The reorganization of community medicine in the SE LHU also provided for the development of intermediate care. At first, the facilities involved were mainly private structures which were accredited to work with the public healthcare system.

Discussion

The SARS-CoV-2 pandemic proved to be an opportunity to refine models of integration among the Department of Disease Prevention, Community Medicine and Hospital Healthcare.

Our results show that slightly fewer infections occurred in the SE LHU. At first, the number of swabs available to each institution was very limited; thus, the authorities opted to carry out swab tests only on symptomatic patients. Nevertheless, in the time-frame examined, 97.16 swabs per 1,000 inhabitants were taken in the SE LHU, which was higher than the mean value recorded in the whole Tuscany Region (86.91 per 1,000 inhabitants) and the national mean of 93.4 per 1,000 inhabitants. However, since the SARS-CoV2 virus is transmitted via droplets between people who are close to each other, the number of positive cases could have been affected by the geographical characteristics of the different territories in the region. Indeed, the SE LHU has the lowest population density (15) in the region, and some areas have very low infrastructure scores (Siena 47 for railways, Grosseto 49 for roads).

The activity of the Tracing Center set up by the SE LHU, which involved 100 operators, including doctors, nurses, health technicians and students, enabled COVID-19-positive patients to be promptly isolated and their network of contacts to be investigated, thus preventing the further spread of contagion. In this regard, it has already been proved that integrated public health interventions within communities, such as testing, contact tracing, quarantining, self-isolation and active surveillance, are key factors in breaking the transmission chain (17). In many healthcare systems, however, the actions of public health services and healthcare operators are uncoordinated, which reduces the efficiency of preventive measures. The implementation of testing and contact tracing is a case in point that clearly illustrates the reason why public health and healthcare systems must act together in a coordinated manner. Indeed, a coordinated system, such as a COVID-19 center, allows more precise analysis of the population, a more efficient use of resources in the field and the rapid review of the effectiveness of the strategies adopted to contain infectious diseases. This is further proven by the heterogeneity of COVID-19 containment strategies worldwide: many countries have relied on passive testing strategies (whereby symptomatic individuals show up voluntarily for testing), an approach that produces different results from those yielded by a proactive strategy involving thorough contact and community tracing and prompt testing (18).

The SE LHU also had a lower fatality rate in the first wave: 6.9% in July 2020, versus 10.8% in the overall Tuscany Region. Moreover, in comparison with other regions, such as Lombardy (18%), Emilia Romagna (15%) and Campania (8.8%) and Italy as a whole (14.4%), the difference was marked (6,19).

One of the main factors underlying the low fatality rate in the SE LHU may well have been the interventions implemented by the USCA teams. Each USCA team worked in close collaboration with General Practitioners, Family Pediatricians and various specialists, such as those involved in the Community Pneumology network, the Infectious Diseases Units and the Community Geriatric network; this enabled a multidisciplinary approach to be adopted in the treatment of COVID-19 patients at home.

The USCAs also made use of telemedicine and telemonitoring tools, which enabled them to manage positive patients with mild or moderate symptoms at home through the real-time detection of vital parameters and their transmission to the territorial emergency services (20). Indeed, telemedicine allows patients to remain in contact with doctors and healthcare services, regardless of how far away they live and how hard it is for them to reach a healthcare provider. Moreover, telemonitoring provides real-time gathering of vital parameters 24/7, thereby allowing emergency services to check on the patient if an altered vital parameter is detected.

Thus, the COVID-19 pandemic revealed that the development of digital healthcare must be a priority and that further investment is required in order to undertake the treatment of patients in their own homes, whenever this is possible, and to avoid unnecessary hospitalizations. For this reason, the Next Generation

EU program, i.e. the investment plan drawn up by the European Union to help the countries hit by the pandemic to rebuild, contains specific provisions for the adoption of digital healthcare technologies, such as teleconsultation, telemonitoring and telemedicine (20-22), and massive funding has been allocated to digital healthcare projects. In this perspective, the telemonitoring experience in the SE LHU proved that digital medicine can efficiently improve the home treatment of patients.

In addition, the SE LHU promptly rearranged the structure of the hospital network in its area. Setting up a separate "pathway" with dedicated beds for COVID-19-positive patients enabled the pressure on hospitals and their emergency departments to be reduced. This strategy was also adopted in hospitals nationwide and worldwide in the shortest time possible, in order to avoid the spread of the disease both among inpatients and among healthcare workers (23-26).

Dedicated COVID-19 beds were also created in intermediate care services, enabling more appropriate care to be provided for positive patients who could not be treated at home but who did not require hospitalization. This helped to alleviate pressure on the Emergency Departments (EDs) and to reduce the intensity of use of emergency health services, since the availability of a pre-hospital, pre-ED level of care meant that they were no longer obliged to transport COVID-19 patients to the EDs.

A study by Specchia et al. found that in those Italian Regions where specific home-care programs had been implemented before the pandemic, fewer COVID-19 patients were hospitalized when the pandemic started. This can be ascribed to the experience previously gained and the fact that the existing programs could be tailored to the management of COVID-19 patients at home (27).

The present study provides an example of flexibility as a key factor in the re-assessment and reconfiguration of healthcare in the community. A flexible model allows healthcare systems to adapt to changing needs and to deploy available resources appropriately within a reasonable time-frame (28). Indeed, the "structural contingency theory" indicates that organizations that address environmental uncertainty early are likely to be more effective (29) in dealing with unexpected issues (30).

One limitation of this study was the inability to further process specific data in order to reinforce our hypothesis. Nevertheless, the study demonstrated that data on death-to-case rates can be used to assess the effectiveness of organizational models of healthcare. Moreover, these data were limited to a single region; a nationwide comparison might help to further assess the effectiveness of this model. However, this would prove difficult, as Italy's healthcare system is region-centered; thus, a nationwide comparison would be biased, owing to inter-regional differences in regulations and health governance models. For this reason, we decided to restrict our study to a single region, as this would allow us to better identify the kinds of actions that can actually reduce fatality in infectious diseases such as COVID-19.

Conclusions

The first wave of the COVID-19 pandemic found many countries unprepared to manage the emergency; the low death-to-case rate recorded in Tuscany's SE LHU demonstrates that the strategy adopted for the management of positive patients was effective. The organizational model, which was coordinated by the LHU health management staff, was made possible only through an important teamwork. This model of collaboration and networking between hospitals and community medicine was already operational in the pre-COVID-19 era. Further crucial elements were: multi-professional integration, organizational flexibility, telemonitoring, teleconsultation, the use of digital platforms for monitoring and management, in-field training, institutional alliances, communication and personal contact.

In conformity with the new territorial healthcare reform prescribed by DM 77/2022 (31), the work carried out by Tuscany's SE LHU during the first wave of the COVID-19 pandemic laid the foundations for better community and home patient management.

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Ethics Approval: N/E

Legend
LHU: Local Health Unit
SE LHU: South-Eastern Tuscany LHU
NW LHU: North-Western Tuscany LHU
CT LHU: Central Tuscany LHU
ICU: Intensive Care Unit

COPD: Chronic Obstructive pulmonary disease
ARS Toscana: Regional Healthcare Agency
SE: Standard Error
Z: Statistical test
USCA: Special Continuity-of-Care Units
E.D.: Emergency Departments
DM: Ministerial Decree

Riassunto

Analisi del modello organizzativo di gestione della prima ondata di COVID-19 nell'Azienda Sanitaria Toscana Sud Est: potenziamento dei servizi territoriali a seguito del Decreto Ministeriale 77/2022

Introduzione. Alla fine del 2019 un nuovo virus chiamato Sars-Cov-2 inizia a circolare a Wuhan in Cina. Lo scopo di questo studio è valutare l'impatto della prima ondata della pandemia da COVID-19 sul sistema Sanitario della Regione Toscana e la risposta messa in atto da parte dell'Azienda Sanitaria Locale Toscana Sud Est anche in vista della nuova riforma di presa in carico territoriale con il Decreto Ministeriale n.77 del 2022.

Metodi. I dati sono stati presi dal database OpenToscana dal primo caso registrato in Italia (18 febbraio 2020) a luglio 2020. Abbiamo analizzato i contagi ed i morti per ogni Azienda Sanitaria Locale della Regione Toscana. Quindi, è stata calcolata la letalità (numero di morti/positivi x100) dell'infezione da COVID-19. Abbiamo successivamente confrontato la letalità tra le Aziende Sanitarie Locali utilizzando il test di Kruskal Wallis.

Risultati. L'Azienda Sanitaria Locale Toscana Sud Est, rispetto alle altre Aziende ed alla media Regionale, nella prima ondata ha avuto un minor numero di contagi (in totale a Luglio erano 1532) e minor numero di morti (in totale a luglio erano 107). La letalità a Luglio era del 6,98%. Il confronto della letalità tra le varie Aziende e la media regionale ha mostrato differenze statisticamente significative ($p<0,001$).

Conclusioni. I modelli organizzativi messi in atto precocemente dall'Azienda Sanitaria Toscana Sud Est per una buona presa in carico territoriale e gestione dei pazienti COVID-19 positivi, ha permesso di limitare la diffusione dei contagi, di conseguenza i decessi e quindi aver avuto una minore letalità nella prima ondata di pandemia.

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