
From Health Care Services to Healthcare Profiling within the COVID-19 Emergency: The Role of the Health Quality Impact Assessment inside the Local Health Unit

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Abstract:

Purpose: *The work considers the application of the quality of the care profile in hospital care, trying to obtain an overview of the resources used in the entire emergency management process in order to understand the information necessary for setting up improvement of activities. The analysis, combines theoretical reflections and empirical evidence relating to the treatment of the COVID-19 virus, develops the approach in question within the complex process of establishing a more effective and efficient care path.*

Design/Methodology/Approach: *The choice of the field survey, is based on the qualitative method and in particular through the use of the case study, finds justification with the study objective and with the nature of the phenomenon investigated. This method lends itself to the need to observe the phenomena being analyzed in the environment of natural manifestation, even in the presence of other variables such as, the peculiarity of the managerial approach of the structure being investigated. Taking into account the current lack of knowledge on the subject being analyzed (COVID-19), the research is also based on a study of exploratory cases. Exploratory studies are appropriate when the understanding of the phenomenon under analysis from a theoretical (clinical) point of view is still in the embryonic stage. More generally, case studies are aimed at understanding complex organizational phenomena. The investigation concerns the Alfa Hospital in Calabria, selected as a study unit on the basis of some considerations. From a territorial point of view it operates in a vast provincial area. The strong focus on share capital is an important element in relation to the issue of quality as it represents a meta-condition for starting efficiency and planning processes. In addition, from an organizational point of view, the Company participated as a partner in projects on issues relating to emergency management. The Company is the regional reference hospital, DEA II level, regional HUB headquarters and COVID-19 Center. It is the reference point of the SPOKE centers, ensuring the highly specialized functions related to the emergency / urgency, coordinating the activity of the networks at local-regional and national level.*

Findings: *The research focuses on the collection of data that represent the effort made by the Company in the construction of a theoretical-practical framework that acts as a reading key for the interrelation of emergency management with the Company's specific organizational-management model within the path concerning the provision of health services and the related care profiles having as central inspiring logic the centralization of the patient.*

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Practical Implications: *Consistent with what happened in other sectors of the Public Administration, where the process of change has as its objective the search for efficiency and efficacy, in Italy there is growing awareness that an efficient, effective and fair health service must be considered a critical success factor for the economic and social development of the country. The health system is at the center of great attention, having to demonstrate that it is adequately using the constantly decreasing resources available to it, in the face of a growing demand for health.*

Originality/value: *The need for a growing orientation towards performance and the use of programming tools in the healthcare sector has been consolidated in the overall process of public administration corporatization. In this context, pathologies characterized by the length of care paths and high complexity in terms of treatment and complications must be considered. These pathologies are important in epidemiological terms, absorbed resources and potential for improvement from the point of view of intervention policies, public health services and efficiency.*

Keywords: *Quality, assistance, healthcare, company, programming, emergency, service, COVID-19, efficiency, management, hospital.*

JEL classification: *M1, M10, M14, I1, I10.*

Paper Type: *Research study.*

1. Introduction

The higher purpose of any Government is to promote the dignity of its citizens, avoiding the identification of people like mere tools to reach political and financial objectives. If any Government considers people as an absolute value and wants to grant their dignity, it must ask itself what are their ambitions and their qualities. Only by trying to answer these questions it will allow them, available resources permitting, to satisfy their ambitions. In other words, to promote the dignity of a nation means to guarantee its citizens the capability and freedom to make and implement their own choices. Obviously, such capability depends from individual abilities (influenced by genetics and by environmental factors), from the political, social and financial context and, indeed, from the general health conditions. It is the indicators related to our state of health that allow the Country to enhance us; the life expectancy at birth, the quality of life free from diseases and disabilities, the ability to keep a good state of health, the psychological well-being, the possibility to express feelings and emotions, the attitude toward environmental preservation.

Governments, therefore, need to invest in the health systems in order to grant their citizens the freedom to fully realize objectives and ambitions, because the higher purpose of a healthcare service is to offer its users the best opportunities to choose the life they desire. In this view, it is useful to refer to the capability approach, a tool to evaluate the wellbeing of people and the social policies aimed at implementing it. According to this approach, development is not intended as financial growth, but rather as human progress, the realization of which cannot overlook fundamental

elements such as freedom, wellbeing and health. The capability approach applied to health allows the identification of the higher purpose of a healthcare system, confirming the relevance of the healthcare policies as the foundation on which lies the commitment of the Governments to grant dignity for all citizens. This is why the success of a healthcare service, together with the measurement through classifications and indicators, must be evaluated also on the basis of the freedom that our state of health allows us in order to choose the life we wish to live (Previtali, 2018).

In this context, the Italian National Health Service (S.S.N.) ranks second in the world for level of assistance (Table 1), continuing to be characterized by the high quality of the services (Bloomberg, 2020).

Table 1. Index of the level of assistance per population, year 2020.

Rank	Country	Health Grade	Population 2020
1	Spain	92.75	46.754.778
2	Italy	91.59	60.461.826
3	Iceland	91.44	341.243
4	Japan	91.38	126.476.461
5	Switzerland	90.93	8.654.622
6	Sweden	90.24	10.099.265
7	Australia	89.75	25.499.884
8	Singapore	89.29	5.850.342
9	Norway	89.09	5.421.241
10	Israel	88.15	8.655.535
11	Luxemburg	87.39	625.978
12	France	86.94	65.273.511
13	Austria	86.3	9.006.398
14	Finland	85.89	5.540.720
15	Netherland	85.86	17.134.872
16	Canada	85.7	37.742.154
17	South Korea	85.41	51.269.185
18	New Zealand	85.06	4.822.233
19	United Kingdom	84.28	67.866.011
20	Ireland	84.06	4.937.786
21	Cyprus	83.58	1.207.359
22	Portugal	83.1	10.196.709
23	Germany	83.06	83.783.942
24	Slovenia	82.72	2.078.938
25	Denmark	82.69	5.792.202
26	Greece	82.29	10.423.054
27	Malta	81.7	441.543
28	Belgium	80.46	11.589.623
29	Czech Republic	77.59	10.708.981
30	Cuba	74.66	11.326.616
31	Croatia	73.36	4.105.267
32	Estonia	73.32	1.326.535
33	Costa Rica	73.21	5.094.118
34	Chile	73.21	19.116.201
35	United States	73.02	331.002.651
36	Bahrain	72.31	1.701.575
37	Qatar	71.97	2.881.053
38	Maldives	70.95	540.544
39	Lebanon	70.53	6.825.445

40	Poland	70.25	37.846.611
41	Montenegro	69.69	628.066
42	Bosnia and Herzegovina	69.66	3.280.819
43	Albania	68.04	2.877.797
44	Brunei	67.96	437.479
45	Slovakia	67.28	5.459.642
46	United Arab Emirates	67.14	9.890.402
47	Uruguay	65.66	3.473.730
48	Hungary	64.43	9.660.351
49	Oman	64.07	5.106.626
50	Panama	64.01	4.314.767
51	Turkey	62.81	84.339.067
52	China	62.52	1.439.323.776
53	Mexico	62.09	128.932.753
54	Argentina	61.19	45.195.774
55	Serbia	60.99	8.737.371

Source: Bloomberg 2020, Healthiest Country index.

At the marking point of 40 years², as “majority stakeholders” we all have the duty to protect the S.S.N., each of us according to their responsibilities, both public and private, cementing a new generational agreement, to pass down to our children the most valuable inheritance, a public, universalistic, and equal healthcare service. Because public healthcare is like healthcare itself, one realizes it exists only once it is lost.

In this context must be considered diseases characterized by the length of the healthcare assistance journeys and the high complexities in terms of treatment and complications. Such diseases have relevance in epidemiological terms, but also in terms of employed resources and improvement potential from the point of view of the intervention policies, of the public healthcare offer and of the efficiency (AA.VV, 2014). The above may refer to the healthcare emergency still in place (although weakened) following the spread, in our Country, of the COVID-19 virus, which is harshly testing the endurance of the National Healthcare Service, employing an enormous amount of resources from both a human and a financial point of view (Comite, 2020).

This work considers the application of the quality of the healthcare assistance profile within hospital assistance, trying to obtain a full frame work related to the resources employed across the entire management journey of the emergency to the purpose of understanding the necessary information in order to set up activity improvement policies. The analysis, combining theoretical considerations and empirical evidence related to the treatment of COVID-19, develops the approach described within a complex process of creation of a more efficient and effective healthcare assistance plan. The proposed model is based on the analysis of the processes, the advantages

²On 23 December 1978 the Italian Parliament approved, supported by a huge majority, the regulation no. 833, which established the National Healthcare Service (SSN) in implementation of art. 32 of the Constitution. Regulation dated 23 December 1978 n°833, *Istituzione del servizio sanitario nazionale, publ. in GU n°360 dated 28-12-1978, Ord. Suppl.*

of which reside in the opportunity to obtain an overall framework related to the resources employed within the entire healthcare assistance plan, for the purpose of obtaining the information needed to set up activities improvement policies and, consequently, resource employment policies. The empirical analysis, related to the healthcare assistance treatment of patients infected with COVID-19, develops the approach in the object in order to identify assistance plans that are more efficient and inexpensive.

2. The Orientation toward the Healthcare Assistance Profiles

The healthcare authorities, by nature, are characterized by a high level of complexity; indeed, they have to manage relevant resources (human, instrumental and financial) for the purpose of guaranteeing heterogeneous and technically advanced services. In their production activity, the healthcare professionals assume a key role, since the quality of the services provided is a function of their experiences, competences, knowledge, quality and behaviours. It is possible to identify two different types of competences needed by healthcare professionals: on one side, the competences linked to clinical assistance activities, on the other, those linked to the typical corporate decision-making processes. The specialty-professional competences are the by-product of a training process that has its roots in Graduate and Post-graduate education, and that grows with field experience linked to clinical and healthcare processes. The management and organizational competences derive from the field experience and from ad hoc training activities (Osservatorio Nazionale sulla Salute nelle Regioni Italiane, 2017).

The methodological approach exam used in the research imposes the consideration of some starting factors. First of all, there are diseases that stand out because of the length of the treatments and the high complexity in terms of treatment and complications (for example, severe haemorrhage, strokes, cancer, and, currently, the treatment of a patient infected with Covid-19). Such diseases demonstrate a considerable relevance in epidemiological terms, but also in terms of employed resources and improvement potential from the point of view of the intervention policies, of the efficacy of the public healthcare offer and of the efficiency (Barsanti and Nuti, 2014; Birley, 2011; Boeckxstaens *et al.*, 2011).

A further aspect to be considered is that the healthcare system is characterized by a type of sectorial organization, in which, special relevance is assumed by the specialization of its functions. In this context, the citizen may independently decide for the request of a first level service, whereas the following ones are submitted to the independent judgment of the general practitioner, although the user is granted the possibility to choose the professional or the second level organization he wants for the fruition of the service (Anselmi, 1990; 1996; Borgonovi, 2013). If on one hand this system grants the possibility, for the patient, to freely choose, and a relative ease in obtaining services, given the high distribution, on the territory, of the offer points, on the other hand, the adequacy of the services does not often reach adequate levels,

causing an increase in the waiting time. For institutional, organizational, behavioural reasons, and also for reasons related to the image of the GPs, the relations between these and the related Local Health Authorities and/or Offer Points are fragmented, not organically oriented and mostly based on a bureaucratic logic (although the involvement initiatives have progressively increased). The communication between the various intervention areas is, therefore, often scarce and, at these conditions, the plan followed by the patient rarely shows adequate integration levels (Foglietta, 2020).

A third element to take into account is that, in a situation such as that of health authorities, in which the integration between competences and components (territory and hospital) becomes a determining factor for the satisfaction of one's needs, the identification of the interdependence amongst the activities, and, therefore, of the processes, becomes essential in order to activate adequate control modalities or to proceed to the redesign, to the purpose of improving coordination in quantitative, qualitative and temporal terms. (Del Bene, 2000; Marinò, 2001).

Despite the growing sectoring of the knowledge and its main depths, often, the satisfaction of a healthcare need implies, even in coherence with the organization of the National Healthcare System, the participation of several units and professionals. The result is often a fragmentation of the assistance plan through which the patients obtain all the services needed in order to respond to their needs. Sometimes, the lack (total or partial) of protocols or guidelines makes it further complex to coordinate the units involved in the production of the overall services. The management difficulties deriving from this entail long waits to obtain a service, duplications of surgeries, process lengthening, all due to a loop in which the patient finds himself involved, passing from one unit to the other. For the National Health Service this may determine an increase of the financial burden due to the lack of coordination existing amongst the units, which often leads to the creation of facilities that are oversized compared to the real needs (Borgonovi, 2013).

For this purpose, all the literature has highlighted the possibility to apply the logic by processes management, (Manganelli and Klein, 1995; Merli and Biroli, 1996; Hammer and Champy, 1995; Borgonovi, 2013), which, in the healthcare sector, has already found many application with reference to the assistance profiles or to the so-called "treatment plans" (Bard, 1994; Carmichael, 1994; Griffit, 1994; Zimmermann, 1994; Casati, 1999), and which results to be an in-progress subject in relation to the several situations it is applied to. The search for managerial and logic tools based on the healthcare assistance profiles places itself in a prospect of strategic analysis, which focuses transversal dimensions of the production processes, in order to monitor the performance of some organizational areas, constituted by the functional or processing aggregation of operational units concerning hospitalization and territorial area. In this respect, it is possible to assess the results of organizational areas that include operational units belonging to a scope of homogeneous activities (for example, the Department of surgical treatments, or the

C.O.U. of Anaesthesia and Intensive Care – that belongs to the emergency department), or of transmural aggregations that coordinate activities related to operational units at the beginning or at the end of a service process and that are dislocated on the territory and in hospitals.

Even in medical literature there are some approaches inspired to the logic by processes, particularly there are reference to disease management and case management. Disease management is a methodology based on an integrated approach to the disease, meant to improve clinical results and quality of the services offered to the citizen in view of a rationalization of the expense and of the efficiency of the treatment, responding to the need to qualify the treatment process through the adoption of a systemic approach finalized to the improvement of the outcomes against an overall reduction of the healthcare costs. It proposes an integrated and coordinated management of the continuum of healthcare assistance, starting from the moment the disease manifests itself up until it disappears. Case management, instead, may be defined as a “systemic approach to healthcare assistance” that has as objectives “the attention to quality and to the continued healthcare assistance provided, the decrease of the fragmentation of the healthcare assistance amongst the improvement of the quality of the different healthcare facilities, the improvement of the quality of life of the user/patient, the containment of the costs” (American Nurse Association Council of Community Health Nursing, 1991).

Case management is, therefore, a personalized process of assistance for patient at high risk associated with treatment costs, that has the purpose to guide professionals in the definition of an adequate assistance plan in the preparation of the coordination modalities that mostly respond to the need of the “case”, in the designing of plans and programs able to improve the quality and the efficacy of the health-and-social interventions, to control the costs and to optimize results (Trincherio, 1999; Kathol, Perez, and Cohen, 2014). The main differences between the two methodologies refer to:

- 1) The object of reference, which, in the disease management is the disease, while in the case management is the single case or patient;
- 2) The moment of the intervention, because while the case management faces patients that show extremely serious diseases to which are associated high treatment costs (severe arrhythmias, radiotherapy, etc.), the disease management tries to intervene in a preceding moment in order to prevent the disease from becoming chronic or degenerating.

In both cases the diseases are associated to assistance paths characterized by particularly high costs. The two methodologies show many contact points where the achievement of the awaited results derives from the designing of an assistance plan that guarantees: 1) an adequate coherence with the need that has to be satisfied; 2) continuity in the assistance; 3) integration and coordination between the various interventions and operators that participate within the process; 4) the quality and

efficacy of the interventions; 5) the attention toward the employment of the resources; 6) the empowerment of the patient, that is made competent in managing (where possible and where is able to), together with the doctors, his disease.

In both cases the process, or a part of it, according to the type of intervention, is addressed to the creation of an added value obtainable through prevention, through the appropriateness of the diagnosis, treatment and rehab plans, through the education of the patient, through the elimination of the squandering deriving from duplications, overlapping and lack of coordination of the interventions.

Case management may assume different extensions according to the territorial setting, or the hospital/territorial setting or just the hospital one. The management of the patient is usually entrusted to a case manager with different competences according to the models adopted. The study of the paths that are more adequate to the needs, highlights the problem of the appropriateness of the treatment and the need for an approach to disease in relation to its peculiarities and not responding in an undifferentiated manner, for example, to the needs of chronic and acute patients. The starting point to set up a management oriented toward the processes is to understand what the available paths for the identified diseases are. In truth, it is opportune to underline that a structured approach to the treatment might not be already.

The approaches might be based on an external or internal orientation. In the first case, the analysis is conducted designing the processes starting from the demand, highlighting, therefore, those deemed necessary in order to satisfy the spotted needs; they will be then classified in primary, supporting or managerial, according to the assumed role. According to the second prospect, instead, the processes are identified starting from the existing organizational structure. It will then be conducted a check of the activities that are carried out within the various organizational units and that are meant to treat the considered disease. Within the scope of this research, an integrated analysis modality has been chosen, since a check of the activities conducted within the various organizational units that are aimed at the attempt to treat the disease that is the object of attention, has been carried out (COVID-19).

Once ended the surveying phase of the present situation, related to the response modality of the company to the needs, it will be about designing (or re-designing) the assistance plan according to the improvement objectives following the analysis of the criticalities. From the conceptual point of view, the design of a new plan should start by putting at the centre of the analysis the needs of the patients around whom the diagnosis-treatment-assistance process unfolds (Ruta, 1994).

Furthermore, the patient becomes crucial since he assumes an active role within the scope of the plan, (Normann, 1992; Borgonovi, 2012). It is enough to think, in this respect, to all the situations in which the treatment of a disease provides the patient with the custody of the respect of a certain treatment that has been prescribed, the

efficacy of which depends from the level of compliance with the regulations provided (Baccarani and Ugolini, 2000). Through proper information and education initiatives, the citizens will be able to more consciously and autonomously face the issues linked to their diseases, adopting, even in the choice of facility, of professionals and of services, a more conscious approach. In relation to the structuring of the new plan, we often refer to the Business Process Reengineering (BPR) that can be intended as the “basic resetting and radical redesigning of the business processes, in order to obtain extraordinary improvements in their services” (Hammer and Champy, 1995). It implies, therefore, a view according to which a problem is faced from a zero based position, that is, without referring to the past situation, researching the original causes from which derive the needs for redesigning, and by focusing on these in order to re-design, from scratch, the paths that are deemed to be coherent with the strategic implications and the improvement possibilities of the organization. Therefore, this applies in situations of redefinition of the strategic approach.

More realistically, the spaces for improvement will have to be verified, starting from a given situation that constitutes a limit (or a possibility) for the improvement level obtainable, applying the Business Process improvement more precisely. (Manganelli and Klein, 1993). In this case, the solutions are identified within the strategic setting in place and they tend to improve the flow and the conduction modalities of the activities without radically modifying the content of the processes. The circumstance in which the process has to be elaborated from scratch, in which case it will be a first-time designing, is different. Starting from the scientific evidences, the best feasible plans, related to the context in which they will have to be applied are identified (prevention, diagnosis, treatment, rehabilitation, assistance), to the purpose of obtaining the best health results and optimizing the employment of resources.

Particularly relevant can be considered the existence (or not) of guidelines according to the disease taken into consideration. The guidelines may be defined as clinical behaviour recommendations produced through a systematic process, to the purpose of assisting doctors and patients in deciding the more appropriate assistance modalities by circumstance, synthesising and systematizing the scientific knowledge on the topic, shared with the medical community. It is evident that the guidelines constitute influential behavioural references for the professionals participating in the treatment process. They, therefore, assume a neutral position compared to the concrete application in an organization that will then descend in relation to the peculiar characteristics it shows. The guidelines do not exist as an alternative to treatment paths, which constitute, instead, an application tool that the professionals' community of a certain organization decides to use to face a certain health problem with specific reference to that reality.

Therefore, the factor to consider in the setting of the plan also refers to scientific guidelines of a certain sector, or to consolidated procedures in other realities (Lega,

2003). An important factor is represented by the human, financial and technological resources available to the company (or acquirable by it) that are needed to sustain the redesigning, considering, also, the situation that will be created by the activation of the new procedure. If it is true that, in order to face some diseases, the overall view of the intervention is more important than the single service, and, therefore, the focus is placed on the global optimum rather than on that of the specific activity, it is then necessary to prepare the basic conditions that favour the coordination amongst professionals and amongst the organizational units involved.

One of these conditions is represented by the constitution of a multidisciplinary and multiprofessional workgroup that faces the clinical and organizational issues. The identification of the paths makes it opportune for the entire subject involved in the process to participate (GP, specialists, nurses, and hospital service, territorial and social agents).

From the clinical point of view it will be about facing the more strictly technical issues, sharing the evidences deriving from the medical practice and laying the bases for a homogeneous application of them. In this respect, the multidisciplinary and multiprofessional groups assume special relevance also as a consequence of the fact that the process may provide an integration between prevention, treatment and rehabilitation and, therefore, between professionals and facilities belonging to different levels of the healthcare system: basic assistance, specialty services, diagnostic services, hospital services. The characteristics of the patients, which determine the conditions for the eligibility to access a given plan, or those concerning the provision of certain services or the passage from a unit to the other, will have to be agreed and shared. A particularly fundamental role is taken on by the General Practitioners (GPs) for initial analysis and diagnosis of the causes of the disease; too this purpose it is necessary to provide them both with the necessary know how in order to adequately conduct the tasks requested of them and with the technological means needed for the purpose.

The sharing of the knowledge and of the plan become unavoidable elements for the operators involved to comply with the common needs of the team. In other words, although respecting the professional autonomy, the interested actors homogenize (not adapt) the approach to the problems in the respect of the coherences established on a process level. In the designing (or re-designing) phase, the professionals involved are stimulated to research alternative solutions that may improve the fruition modalities of the overall services needed by the patient in terms of timing, accessibility, and linearity, without neglecting the possibility, all other conditions being equal, to rationalize the usage of the resources. An internalization of the values to which the organizational behaviours should inspire is needed and obtainable through the scientific-cultural exchange regarding the specific problems that will have to be faced (access conditions, facility changing conditions, or conditions related to the diagnosis etc.).

In view of the organizational control aspect, the setting of the process management implies the solution of the issue referable to the identification of the person responsible for the process. The literature on the subject of process reengineering and the operational procedures postulate the need to identify a process owner, that is, the person responsible for the correct functioning and improvement of the process. The objective can be reached through the setup of a co-responsibility amongst the operators that contribute to the conduction of the process, or through the attribution of responsibility to the process owner alone, together with the related organizational power (Brunetti, 1979; Bubbio, 1995; Bergamin and Barbato, 1983; Brusa and Zamprognà, 1991; Gandolfi *et al.*, 2014).

A further necessary condition, aside from the functioning of the system designed, is constituted by the activation of an integrated information system (Saita, 1988; Marchi, 1993; Amigoni and Beretta, 1998) that allows the measurement of the performance of both the single activities and the process. Indeed, having identified the activities and the paths in which they are inserted, without providing the new conditions for their identification and the related characteristics, under the multiple prospects that are deemed to be necessary (economic, financial, physical, technical), makes the previous work useless and the monitoring of the trends impossible.

From this point of view, the information system constitutes an unavoidable support and re-engineering factor, offering a systematic monitoring of both the economic-financial variables and the technical-operational ones (Buccoliero, 1998; Avi, 2019; Pighin and Marzona, 2018) as well as a stimulus to the introduction of organizational and managerial innovations. It is also evident how the activation of an integrated information system affects the control system as well, being it able to raise its information potential and the potential related to its accountability. The exploitation of the information systems implies the existence of a corporate culture sufficiently advanced on the topic as to avoid having to “suffer” the system, by being trapped in its standard configuration, instead of using its potentiality for its own needs (Granlund and Mouritsen, 2003; Scapens and Jazayeri, 2003). Furthermore, as all the projects that have a strategic relevance, since they imply substantial changes in the culture, in the approach and problem solution modality, it is important to ensure the constant presence of corporate management in order to activate, support and continuously validate the initiative.

3. The Treatment of Patients Infected by COVID-19: Empirical Evidence

3.1 Object, purpose and method

The case examined concerns a study conducted to identify the adequate assistance profiles oriented toward the improvement of the therapeutic efficacy and the managerial efficiency of the hospital accesses, with regards to the patients infected with COVID-19 virus, a disease that develops following an infection by Sars-Cov-2

(Coronavirus)³. This choice has its foundation in the peculiar aspects that characterize the accesses in object and that synthetically recall:

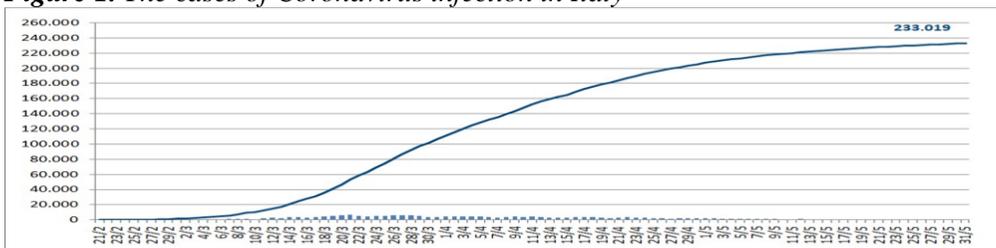
- The first consideration, which concerns the absolute new constituted by this pandemic emergency originated from a virus we know very little about from a clinical and therapeutically point of view, that has certainly put a huge strain on hospitals in terms of human and material resources;
- The second consideration, which concerns the cost of the treatments, considering the diagnosis and treatment plans that can be activated in relation with the disease that has caused it and the high diagnostic risk;
- The third consideration, which concerns the need to identify managerial modalities oriented toward the improvement of the relation between improper hospitalizations and number of accesses, with consequent reduction of the s.c. “useless” hospitalization rate;
- The fourth and last consideration, which relates to the peculiarities of the s.c. “dedicated” intensive care hospitalization, to the purpose of avoiding the

³*The coronaviruses are a large family of viruses known for causing diseases that go from a simple cold to more serious ones, such as the MERS, Middle East respiratory syndrome and the SARS, Severe acute respiratory syndrome. They are RNA positive filament viruses, looking like a crown, when observed on an electronic microscope. The subfamily Orthocoronavirinae of the Coronaviridae family is classified in 4 types of coronavirus (CoV): Alpha-, Beta-, Delta- and Gamma-coronavirus. The betacoronavirus type is further divided in five subtypes (amongst which is the Sarbecovirus). The Coronaviruses have been identified toward the mid '60s and are known for infecting humans and some animals (including birds and mammals). The target primary cells are the epithelial ones of the respiratory tract and of the gastrointestinal tract. To date, seven types of coronavirus have demonstrated to be able to infect humans : a) common human: HCoV-OC43 e HCoV-HKU1 (Betacoronavirus) and HCoV-229E e HCoV-NL63 (Alphacoronavirus); they can cause simple colds but also serious infections of the lower respiratory tract; b) other types of human (Betacoronavirus): SARS-CoV, MERS-CoV and 2019-nCoV (now denominatd SARS-CoV-2). The new coronavirus SARS-CoV-2, is a virus strain that has never been identified in humans before. In particular, the one denominatd SARS-CoV-2 (previously 2019-nCoV), has never been identified before having been observed in Wuhan, China, in December 2019. In the first half of February, the International Committee on Taxonomy of Viruses (ICTV) , which deals with the designation and denomination of viruses (that is species, genus, family, ecc.), has assigned the new coronavirus its final name: “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2). To outline the name there was a group of expert in charge of studying the new strain of coronavirus. According to this pool of scientists the new coronavirus is linked to the one that caused SARS (SARS-CoVs), that's why the choice of the name SARS-CoV-2. Again, in the first half of the month of February (precisely on February 11th) The WHO announced that the respiratory disease caused by the new coronavirus had been named COVID-19. The new acronym is the synthesis of the terms CO-rona VI-rus D-isease and of the year of identification, 2019 (editor's note).*

mixing with patients hospitalized for different diseases that could then be infected.

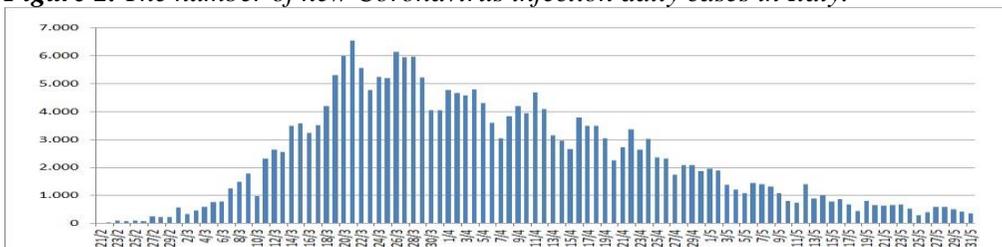
It is also necessary to underline how the contrast of this virus which has significantly affected the population (also and above all in terms of lifestyle) represents, in light of the latest events, one of the health objectives indicated as strategic by the Ministry of Health. Below, the official data from the National Civil Protection Service and from the Italian Higher Health Institute, from 21, February 2020 (date of the issuing of quarantine and active surveillance measures) to 31 May 2020 (date close to the upcoming end of the block of transfers from region 3 June 2020), concerning, the cases of Coronavirus infections in Italy (Figure 1).

Figure 1. The cases of Coronavirus infection in Italy



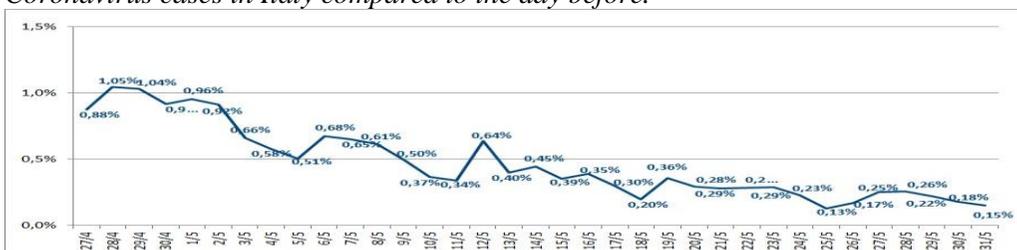
Source: Processing of data from the Ministry of Health and Civil Protection.

Figure 2. The number of new Coronavirus infection daily cases in Italy.



Source: Processing of data from the Ministry of Health and Civil Protection.

Figure 3. The percentage increase (or decrease) of the total number of confirmed Coronavirus cases in Italy compared to the day before.



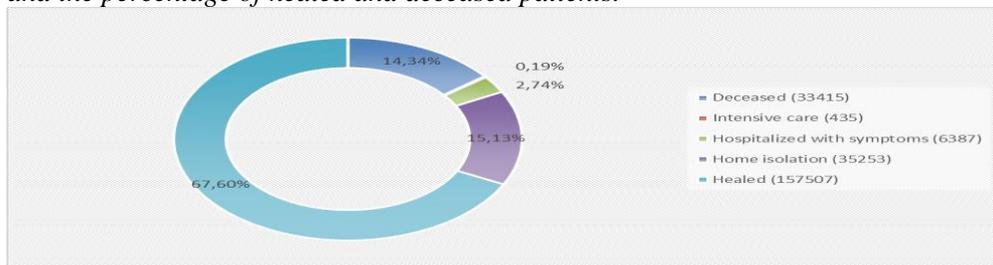
Source: Processing of data from the Ministry of Health and Civil Protection.

Table 2. The geographical distribution of the Coronavirus infection cases in Italy divided by Regions.

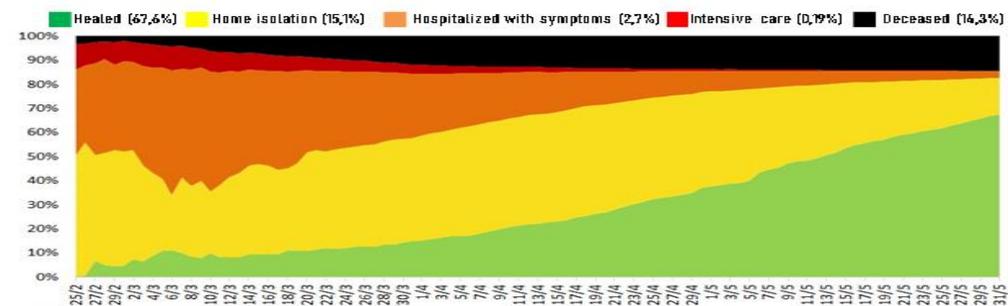
Regions	Update to May 31, 2020									
	Positive to nCOV				Dismissed / Healed	Deceased	Total cases	Total cases increase to the previous day	Swabs	Cases tested
	Hospitalized with symptoms	Intensive care	Home isolation	Total currently positive						
Lombardia	3.131	170	17.695	20.996	51.860	16.112	88.968	+230	753.874	445.930
Piemonte	973	58	4.130	5.161	21.609	3.867	30.637	+54	319.133	207.714
E Romagna	393	57	2.713	3.163	20.513	4.114	27.790	+31	325.482	197.423
Veneto	112	6	1.382	1.500	15.734	1.918	19.152	+6	669.768	333.834
Toscana	97	28	986	1.111	7.952	1.041	10.104	+4	252.090	179.296
Liguria	195	8	466	669	7.529	1.465	9.663	+12	106.363	59.374
Lazio	730	57	2.196	2.983	4.010	735	7.728	+13	255.474	206.235
Marche	62	9	1.267	1.338	4.405	987	6.730	+3	103.634	65.617
Campania	227	5	748	980	3.410	412	4.802	+5	201.543	98.096
Puglia	143	11	1.023	1.177	2.813	504	4.494	+4	118.652	79.314
Trento	13	3	288	304	3.664	462	4.430	+1	88.588	48.665
Sicilia	65	7	914	986	2.183	274	3.443	+1	150.054	128.717
Friuli V.G.	41	1	236	278	2.662	333	3.273	+2	134.378	80.223
Abruzzo	104	4	645	753	2.064	405	3.244	+7	75.652	50.050
Bolzano	13	4	110	127	2.179	291	2.597	+1	Region	30.790
Umbria	15	2	14	31	1.324	76	1.431	0	70.553	50.271
Sardegna	33	2	150	185	1.041	130	1.356	0	57.296	49.016
Val D'Aosta	32	0	3	15	1.026	143	1.184	+1	15.203	11.926
Calabria	22	1	121	144	917	97	1.158	0	70.274	68.015
Molise	2	2	141	145	269	22	436	0	14.631	13.965
Basilicata	4	0	25	29	343	27	399	0	29.880	29.130
Total	6.387	435	35.253	42.075	157.507	33.415	233.019	+355	3.878.739	2433.621

Source: Processing of data from the Ministry of Health and Civil Protection

Figures 4 and 5. The percentage of cases of Coronavirus infection in Italy divided by initial setting (social isolation, hospitalization, intensive care hospitalization) and the percentage of healed and deceased patients.

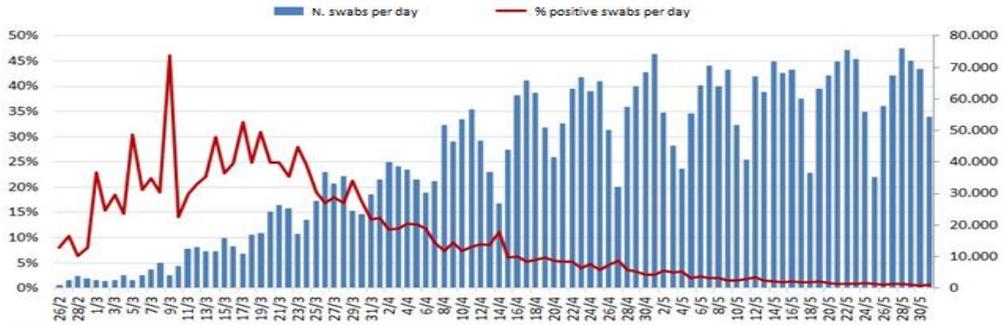


Source: Processing of data from the Ministry of Health and Civil Protection.



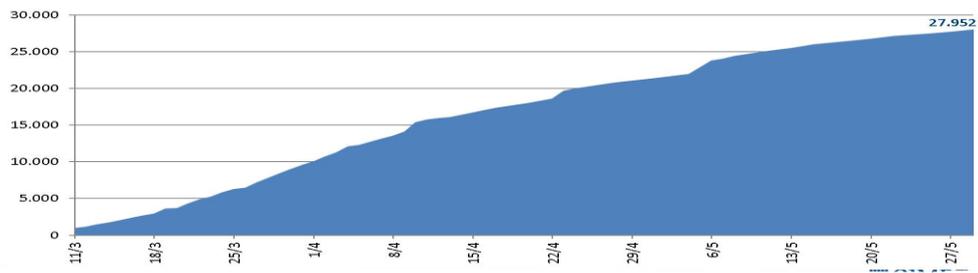
Source: Processing of data from the Ministry of Health and Civil Protection.

Figure 6. The number of tests conducted and the percentage of positive test by day.



Source: Processing of data from the Ministry of Health and Civil Protection.

Figure 7. The number of infected healthcare workers.



Source: Processing of data from the Ministry of Health and Civil Protection.

In this context, one of the main causes of inefficiency (or, more correctly, improvement possibility) in the assistance process has been identified with reference to the inadequacy, both qualitative and quantitative, of the means for prevention and diagnosis (at least in the initial phase) and, nevertheless, in the organization modalities of the first response operational units⁴. The easiness and, therefore, the quickness of the contagion and the consequent need to resort to intensive care in serious cases, has quickly used up all the hospital beds available in the areas hit by the infection, creating a sort of distanced competition for the construction of new hospitals, with an inevitable burdening of expenses for the National Healthcare Service. Unfortunately, this was not enough to stop the shocking number of deaths.

⁴In truth, since until January 2020 we did not recognize the existence of this virus, we must consider that the declaration of the WHO (World Health Organization) of "pandemic", dated 11 March 2020, represents sine dubio an unexpected and unpredictable event (using the ordinary diligence, which cannot be avoided in any way) and configures the so-called Force Majeure which is cause for exemption from liability. From this it follows that the inefficiency (rectius the possibility of improvement) is not attributable to human conduct lacking diligence, and expertise, but rather to facts that go beyond the will of the individual operator (editor's note).

Italy has face a s.c. “catastrophe medicine” situation, characterized by the absence of efficient therapies (s.c. therapy protocol), which entails, to date, a “therapy” for the disease that is faced through the so called support therapy, that is, curing the symptoms through medications meant for other indications (for example: anti-inflammatory, anti-viral, etc) that are made available to the patients, even in absence of a specific therapy for COVID-19. In reference to the assistance system and/or first response system, it is important to underline that the single regions are providing the realization of a network for COVID-19 emergencies functionally integrated with the emergency (118 number) service and with the departments of emergency and admission (DEA) with first aid functions, including several operational units centred on the treatment of the patient in critical areas (hemodynamic, invasive cardiology, intensive care).

The integrated network should favour the concentration of services characterized by more complexities and higher technology, as well as higher accessibility promptness. To this purpose, it is opportune to highlight, on a preliminary count, the two possible paths followed by patient suspected of being infected with COVID-19, in the hospital access: 1) spontaneous submission of the patient 2) emergency access.

In both cases, the access of the patient to the hospital happens in the E.R. or through the DEA (where present), which will conduct the first examinations and that will provide a brief observation and diagnosis hypothesis from which will be decided whether the patient will be dismissed or hospitalized, with related assignment to the competent operational unit (in this case the unit will be dedicatedly denominated “COVID-19 Intensive Care”). If the hospital does not have any available dedicated beds, the hospitalization will be done in another properly equipped facility, even outside the region.

On the basis of the trend of the daily hospitalization, should it show a less critical progression, the patient will be transferred to the so-called sub-intensive care units, where his vital functions will be constantly monitored through less invasive equipment. A class of patients to be added to these last ones is the one constituted by those whom, feeling sick, contact the specifically provided regional emergency number, and take a basic questionnaire given by specifically trained operators. The questionnaire aims at verifying the presence of “suspect” symptoms (dry cough, fever and breathing difficulties) for which a decision can be made, in mild cases, to put the patient in quarantine with recurring monitoring. So it becomes evident how crucial is, for the particular case object of the research, to identify adequate assistance profiles, considering the high cost associated with the treatment.

3.2 ALFA health unit: features

The research has concerned the ALFA Health Unit in Calabria, which consists of one hospital centre only, according to the observation of the data from 21 February 2020 to 31 May 2020, divided in three hospital facilities for a total of 1000 beds.

The unit has been selected as study unit on the basis of a few considerations. From a territorial point of view it operates in a vast province. The strong attention to the share capital constitutes an important element in relation to the topic of quality, representing a meta-condition needed to start efficiency and programming paths. Furthermore, from an organizational point of view, the Unit has participated as a partner in projects regarding emergency management. The Unit is made of 41 complex facilities, 12 department facilities, 53 simple facilities, 7 complex operational units in the technical and administrative area, it employs 5000 people and counts 600 doctors. The population potentially assisted is 700.000 inhabitants distributed in 155 municipalities.

The Unit is the regional hospital of reference, II level DEA, HUB regional office and COVID-19 centre. It is a reference point of SPOKE centres, ensuring high specialization functions linked to the emergency/urgency, coordinating the activity of the local, regional and National network. Being an HUB centre, it ensures the high specialization functions linked to the emergency/urgency and, therefore, it coordinates the networks' activities (for example intensive care and critical anaesthesia activities) to the purpose of granting prompt diagnosis and appropriate treatments, providing diagnostic and treatment services that cannot be conducted in SPOKE centres.

The Unit promotes new strategies and tools finalized to create, maintain and develop a network of services, integrating social-health services and hospital-territory services even in intra-firm modality, to the purpose of granting the most efficient and complete assistance paths and the continuous improvement of the quality of the services. For the social-health integration, the Unit cooperates with the bodies of the Provincial Health (ASP), to the purpose of agreeing the guidelines and the behavioural instructions when taking charge of the patients dismissed from the hospital. The Unit, in accordance with its role of relevant regional high specialization facility and in respect of the indications provided by the Regional Department for the Protection of Health regarding the course of abatement of inappropriate hospitalizations in hospital facilities, offers diagnostic assistance and specialty treatment services to the users, within the territory, that resort to the Health Unit even through the service made available by the Emergency/Urgency area. The Unit, through a specific integration activity scheduled with the Provincial Health Unit, is committed to the realization of specific assistance paths within the integrated management of patients in need of diagnosis and treatment, with a disease of any type in advanced state. Therefore, the unit pursues, primarily, the continuity objective of the treatment paths, intended as globally taking charge of the patient and as an integration of all the stages of the plan. The continuity of the treatment paths in the framework of hospital assistance is realized through the departmental organization of the unified hospital unit and for the channel of integration of the departments that compose it together with the territorial districts, even tank to the previous agreements between Hospitals and Provincial Health Units.

3.3 Methodology of the research

Taking into account the current scarce knowledge of the topic object of the analysis, this work is based on an explorative case⁵, it analyzes the tools and processes through which it is possible to evaluate the impact on the quality of the health of the patient within the diagnostic-therapeutic-assistance plan provided by the Health Unit, to the purpose of proposing (possible) margins for a streamlining and an improvement of the plan in place. The analysis of the “if” and “how” the principle of the quality of health is translated into practice is particularly relevant in health units, even in view of the limited resources available to take in a growing health demand, such as the one deriving from the pandemic object of the analysis. Indeed, because of the tensions between cost containment objectives on one side, and treatment circulation on the other, the course of translation of the principle of quality from the abstract sphere of thought to the concrete dimension of the organizational practice may reveal itself to be particularly complex (Macinati and Pessina, 2014). The access to the case has been obtained through documents provided by strategic management. The classified material has been subsequently interpreted.

3.4 Empirical analysis on the Alfa Health Unit

The company commitment in theme of quality and the diagnosis-treatment-assistance plan have been carried out as explained below, with the objective of planning and realizing organizational diagnostic actions. The study has been conducted on patient that get to the E.R. operational unit, not exclusively because of the disease in place, but only because of one or more symptoms, according to which, the case is classified (suspect, probable and confirmed) as provided for by the Ministerial memorandum n°7922 dated 9 March 2020.

After a test is conducted on a patient, the diagnostic and CE-IVD e/o EUA/FDA (Point of Care tests, POCT) molecular analysis, based on the observation of viral genes directly in the respiratory secretions, are carried out, allowing the obtainment of results in very short times; these tests, which are able to presently process only a few samples at the same time, are useful in cases in which the Coronavirus infection diagnosis becomes urgent. The conduction of the test is reserved primarily for symptomatic clinical cases or cases with mild symptoms and for their contacts at risk, such as relatives and/or people living with them, focusing the identification of the contacts at risk in the 48 hours prior to the beginning of the symptoms in case of a positive or clinically suspect case, as per memorandum n°9774 dated 20/03/2020. In the month of February-March 2020, anticipating a wide COVID-19 contagion, and in the case in which the lab capacity would not be enough to conduct the analysis provided for by the memorandum dated 20 March 2020, the possibility was

⁵*In Business Management, the use of case studies results to be the more appropriate methodology for the study of complex realities, such as the one related to local health units, having an advantage the facto of providing indications based on concrete evidence, rather than theoretical (Ryan et al., 2002). Case studies allow, therefore, the filling of that gap that often exists between theory and practice (Chiucchi, 2014).*

evaluated, to further enlarge the number of additional labs, creating a coordination between hospitals and regional labs of reference, also considering the possibility to use mobile labs or drive-in clinics, consisting of testing facilities able to obtain samples through an open car window at the entrance of the hospital from a suspect patient sitting in the car. These actions have made it possible to reduce the infection risk for the healthcare personnel or for other patients, preserving the ability of the labs to conduct diagnostic tests and surveillance activities for other diseases.

In case of need, for example, because of the accumulation of samples to be analyzed with a related delay in the response, lack of reagents, impossibility to securely stock the samples, work overload for the lab's personnel, and so on and so forth, priority was given to the conduction of tests to hospitalized patients with severe acute respiratory infection (SARI), to the purpose of providing indications on the clinical management, including the possible isolation of the case and the employment of appropriate Individual Protection Equipment (DPI) as indicated by Memorandum n°5443 dated 22 February 2020. In order to optimize resources, the following modalities have been adopted:

- conduction of one pharyngeal-nose test for each patient;
- conduction of one test from many samples on a single patient, united in one only
- diagnostic sample;
- the patients that have already been confirmed as testing positive have not been submitted to further COVID-19 tests until the moment of the clinical recovery, which must be supported by absence of symptoms and negative SARSCoV-2 pharyngeal-nose test repeated twice in 24 hours before dismissal;
- the presence of a test that is considered undetermined because it is positive to only one gene target in presence of the typical COVID-19 symptoms is to be considered as a COVID-19 case;
- there have not been any tests made without a prescription form a GP or a hospital.

Furthermore:

- all the samples that have tested positive for SARS-CoV-2 in deceased patients are frozen at a temperature of a -80° C in the facility that has conducted the sample/lab analysis and are then sent to the National Reference Laboratory (LRN) at the Higher Health Institute (ISS) upon express request of the same;
- in authorized labs for sample analysis, the presentation of samples from healthcare personnel obtains absolute priority and the communication of the result must be done in a 36 hours time span.

The history of the patient is followed through the filling out of a specific form, which will implement a platform of in-progress data, made of two data fields "Hospitalization Date" and "Result Date". Particularly, the hospitalization date is

used to describe the placement of the patient in the hospital and also the date of dismissal. Currently there is no field for a dismissal date (that is why the second date in the Hospitalization Date filed is considered the dismissal date). The result date is the date of death, when the result is death, and the date of recovery when the result is recovery, there is also a passage of state date, when the patient improves or deteriorates. This leads to another field defined as “CLINICAL STATE” (asymptomatic, mildly symptomatic, mild, acute, critical, recovered, and deceased). It is provided that each clinical passage of state must be monitored and dated (RESULT DATE).

Remaining focused on the clinical state of the subject, there is also a “VENTILATED” (yes/no) field. The possible placement in intensive care is recorded in the information related to the hospitalization, providing also the circumstance in which the patient is ventilated, being it useful to evaluate the employment of lung ventilators.

Another point on which is important to bring our attention is the moment in which the patients are entered in the database. We have two date fields available: 1) SAMPLE DATE, 2) DATE OF THE BEGINNING OF THE SYMPTOMS.

THE SAMPLE DATE is the moment in which the most complete epidemic curve is drawn. However, this date is probably a heterogeneous combination of dates that differs as the lab they come from changes. It may represent the date of receipt of the sample or the date of the recording of it, as it appears from the labels of the epidemic curve reported in the daily info-graphic. There can be a time lapse of a few days between the two.

THE DATE OF THE BEGINNING OF THE SYMPTOMS is the one on which the real epidemic curve is created and by which real trend of the epidemic can be monitored, although in the Hospital observed it is filled out only in 56% of the cases. Despite hypothesizing a certain asymptomatic patients' rate, which makes it difficult to fill out the date, the coverage expected is higher anyway.

A question comes to mind; do asymptomatic patients fall within the epidemic curve drawn according to the beginning of the symptoms or to the sample date? Or do they not fall within this curve at all? At any rate, there should be an awareness work for the best filling out of this field. Some strategic information to draw the trend of the epidemic is the placement of the subject, which can happen through RESIDENCE address and DOMICILE address. This leads to the following topic, which is the possibility, for this information system, to trace the chain of contacts for secondary cases.

There are two fields: “ISOLATED CASE” (yes/no) and “LINKED CASE” (free text). The collection of linked cases as free text field makes the analysis impossible.

This consideration opens a new front for reflection on the profound difference between the very evolved system we have on a national level and the systems that the Prevention Department of the examined unit has developed in order to respond to the emergency, with the consequent need to think of an intense realignment (and, therefore, re-designing) work. The Ministry of Health will have, in the long term (in the transition phase from emergency to the managing phase of an “under control” epidemic). The complexity of the situation makes it necessary to implement forms of participation and discussion in order to develop systems of applicative cooperation that enhance that has already been developed at different levels, avoiding the self-governing risk.

In the current situation, the challenge of the pandemic requires organizational solutions even in the collection of data that keep together national regional and local needs. The plan is very challenging and it collects a lot of evidence and is not always clear on how to use them. In the case under exam, a study sample has been identified, which consists of the accesses from 21-2-2020 to 31-5-2020, for suspect cases of COVID-19. From the E.R. records, integrated with the hospital dismissal records of the department that has hosted the patients, has emerged that on a little less than 1000 accesses, 4% of the patients has shown the symptoms at issue. Amongst these, 56% of them has been dismissed after the first visit, with home quarantine obligation, 44% has been hospitalized in Intensive Care, while the total number of deaths amounts to 33.

3.5 Hospitalization in intensive care

The above counts in case the patient is not in imminent life danger, which allows the dilution of the timings of a possible hospitalization. If, instead, the patients gets to the ER affected by an obvious severe acute respiratory infection, the task force that has been especially created (and constituted by doctors, nurses, paramedics, especially trained to the use of the ventilation systems and to the correct adoption of the PPE) participate, according to the competences of its members, to the hospitalization in Intensive Care, in the special department denominated “T.I. COVID-19”. Such Intensive care unit has been primarily created in the hospital facility equipped with the Infectious Diseases Multispecialty Department.

It is in this precise moment that the Tutor Medic (TM) or the Clinical Tutor (CT) comes into play. These figures are responsible, together with the director of the facility the case is assigned to, for the diagnosis-treatment plan of the patient from the moment of the admission up until dismissal, granting maximum hospitalization efficacy. The TM is a doctor that for a prolonged period of time takes charge of the patients (not the beds) assigned to him (up until an indefinite number) from the Director of the facility, within 24 hours of their access and with criteria that will have to be clarified beforehand (previous clinical records, particular competences etc). The MT exclusively deals with hospitalizations from Monday to Saturday and will have to be, where possible, relieved from guard/availability shifts, outpatient services, etc. The allocation of the patient to the TM is formalized by the OU

director and, in case the patient is admitted in the evening, or at night, or on holidays, the patient will be firstly dealt with by the doctor on duty at the OU or by a departmental doctor on duty. The TM is a reference figure for the patient, his family and the GP, and it is, therefore, the figure that grants the continuity of the diagnosis and treatment plan. He communicates with the nurse of reference of the beds the patients are placed in so as to optimize the assistance.

All the requests for beds in for COVID-19 patients in Intensive Care, after an evaluation conducted by an Anaesthesiologist, are sent to the 118 operational unit, which operates the transfer, providing the vehicle and the related adequately trained crew. Obviously, even in this case, the history of the patient is followed through the compilation of a specific form, which will implement an in progress data platform. After having acquired the clinical history of the patient, at the same time his other previous or current potentially dangerous diseases are excluded (for example, angina, stroke as a consequence of breathing difficulties) (Table 3).

Table 3. *Pre-existing diseases more frequently observed in a relation of comorbidity with the COVID-19 virus.*

Diseases	Women		Men		Total	
	N.	%	N.	%	N.	%
Ischemic Cardiopathy	224	21,1	678	31,7	902	28,2
Atrial fibrillation	245	23,1	462	21,6	707	22,1
Cardiac Decompensation	194	17,7	313	14,3	507	15,8
Stroke	110	10,4	213	10,0	323	10,1
Hypertension	736	69,4	1436	67,1	2172	67,9
Type 2 Mellitus Diabetes	299	28,2	662	30,9	961	30,0
Dementia	242	22,8	267	12,5	509	15,9
BPCO	134	12,6	395	18,5	529	16,5
Cancer active within the last 5 years	172	16,2	339	15,8	511	16,0
Chronic liver disease	30	2,8	99	4,6	129	4,0
Chronic kidney failure	192	18,1	462	21,6	654	20,4
Dialysis	18	1,7	45	2,1	63	2,0
Respiratory failure	54	5,1	109	5,1	163	5,1
HIV	0	0,0	7	0,3	7	0,2
Autoimmune diseases	62	5,8	61	2,9	123	3,8
Obesity	118	11,1	235	11,0	353	11,0
Number of diseases	N.	%	N.	%	N.	%
0 diseases	28	2,6	103	4,8	131	4,1
1 disease	153	14,4	324	15,1	477	14,9
2 diseases	236	22,3	453	21,2	689	21,5
3 or more diseases	643	60,7	1260	58,9	1903	59,5

Source: Ministry of health: data as of 31 May 2020⁶

⁶Table 3 shows the most common pre-existing chronic diseases (diagnosed before the SARS-CoV-2 infection) in deceased patients. This data has been obtained from 3200 deceased for whom it was possible to examine the medical records. The average number of observed diseases in this population is 3,3 (av. 3, standard deviation 1,9). Overall, 131 patients (4,1% of the sample) showed 0 diseases, 477 (14,9%) showed 1, 689 (21,5%) showed 2 diseases and 1903 (59,5%) showed 3 or more. Before the hospitalization, 23% of the deceased

The decision to suspect of concomitant diseases is founded, first of all, on information that has an uncertain clinical meaning and a variable diagnostic importance, while waiting for the diagnostic procedure. It is unusual that a single data, whether clinical or instrumental, is indicative of the disease without being interpreted, even in different ways. Experience is, therefore, crucial to the purpose of the allocation of a decision-making burden that is appropriate for the data gathered that, however, are often probabilistic, unless the physical examination, the diagnostic procedure and the anamnesis of the patient consisting in the ailments reported by him or his family, enrich the framework of the information needed for a final diagnosis.

Furthermore, the Trust has seen to integrate the emergency functions appointed to the management of the same, improving the assistance process, where the benefits of a transfer, for the patient, result to be more evident in relation to the time factor. Also, an integrated 118-Emergency Care model that responds to logics of promptness, appropriateness and continuity of the treatments needed has been realized. As for traumatized patients and for patients affected by non-traumatic diseases with rapidly unfavourable evolution, such as acute disease, the results of which are strongly influenced by the time factor, even for particularly serious COVID-19 patients who live very far from the OP, the helicopter rescue has been used, decreasing, this way, the morbidity due to transport of urgent cases to the OP's end point.

In the beginning, the provision regarding the Coronavirus pandemic and the current situation in some Italian regions, characterized by an increase in the case of severe acute respiratory failure (with need for Intensive Care Hospitalization) so serious as to determine a huge imbalance between the real clinical needs of the population and the actual availability of intensive resources, has placed the challenge on the governance of the Trust object of study, to make it necessary to have some access (and dismissal) criteria to Intensive Care, not just of clinical appropriateness and treatment progressiveness, but also inspired to a shared criterion of distribution justice and appropriate allocation of limited healthcare resources.

Such a scenario falls, as previously affirmed, within the category of "catastrophe medicine". The capacity of the single hospital facility has been increased through the activation of beds, in the critical area, that are presently not being used, recasting the scheduled activity.

patients that tested positive to SARS-CoV-2 were being treated with ACE- inhibitors and 16% were in being treated with Sartani (angiotensin receptors blocker). In women (n=1060) the average number of observed idseases is 3,3 (avg. 3, standard deviation 1,9); in men (n=2140) the average number of diseases observed is (avg 3, Standard Deviation 2,0). Respiratory failure has been the most commonly observe complication in this sample (96,9% of the cases), followed by acute kidney failure (22,3%), superinfection (12,6%) and acute myocardic damage (10,8%).

As an extension of the principle of proportionality of the treatments, the allocation, in a context of great shortage, of the healthcare resources, must aim at granting intensive care treatments to patients less likely to succumb to the disease: it is about preferring the “higher life expectancy.” The need for intensive care must, therefore, be integrated, with other “clinical suitability” elements in the intensive treatments, thus understanding: the type and seriousness of the disease, the presence of co-morbidity, other organs’ damages and their reversibility. This has entailed that there is no need for operating a “first come, first served” access criterion. It is understandable that the healthcare providers, because of their culture and training, are less prone to reason by maxi-emergency triage criteria, because the present situation is exceptional.

The availability of the resources is not normally included in the decision-making process, until the resources become so scarce to not allow the treatment of all the patients that could hypothetically benefit from a specific therapy. It is implicit that the application of rationing criteria is justifiable only after all the involved subjects (particularly the “crisis units” and the managerial bodies of the Hospital Units) have made all the possible efforts to increase the availability of allocable resources (In particular, beds in Intensive Care) and after all the possibilities to transfer the patients to facilities that can count on more resources are evaluated. In the *modus agendi* of the Trust *de qua*, the fact that a modification of the access criteria could be shared amongst all the operators involved has shown to be of crucial importance. The patients involved in the application of the criteria and their families have been told about the extraordinary nature of the measures in place for duty of transparency and of maintenance of the trust in the public health service.

4. The Different Regulatory Provisions Adopted by the Calabria Region within the COVID-19 Emergency

In the Calabria region (the epidemiologic situation of which is illustrated in Figure 8) the following regulatory deeds aimed at the prevention and management of the covid-19 epidemiologic emergency have been issued:

- Ordinance of the president of the region no.1 dated 27 February 2020 – further measures for the prevention and the management of the covid-19 epidemiologic emergency, ordinance pursuant to art. 32, par. 3, of Reg. dated 23 December 1978, n. 833 concerning public health and hygiene. Such provision has provided: a) information and prevention measures (census of re-entries in Calabria); b) further measures for prophylaxis and treatment of the subjects that have stayed in the areas of China, and in the Italian towns where the local transmission of the virus has been demonstrated; c) isolation monitoring; d) surveillance measures.
- Ordinance of the president of the region no. 3 dated 8 March 2020 – urgent measures for the prevention and the management of the covid-19 epidemiologic emergency, ordinance pursuant to art. 32, par. 3 of Reg. dated 23 December 1978, n. 833 concerning public health and hygiene.

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- Ordinance of the president of the region no. 4 dated 10 March 2020 – operational provisions regarding further measures for the prevention and the management of the covid-19 epidemiologic emergency, ordinance pursuant to art. 32, par. 3, of Reg. dated 23 December 1978, n. 833 concerning public health and hygiene.
 - Decree no. 18 dated 11 March 2020 “Further measures for the prevention and the management of the covid-19 epidemiologic emergency: priority activation, for any Area of Reference of the Calabria Region (North, Centre, South) of facilities to be dedicated to the management of patients infected with COVID-19”.
 - Ordinance of the president of the region no. 07 dated 14 March 2020 - further measures for the prevention and the management of the covid-19 epidemiologic emergency, ordinance pursuant to art 32, par. 3, of Reg. dated 23 December 1978, n. 833 concerning public health and hygiene: provisions related to the access of people within the regional territory.
 - Ordinance of the president of the region no. 08 dated 16 March 2020 - further measures for the prevention and the management of the covid-19 epidemiologic emergency.
 - Ordinance no. 4 dated 10 March 2020: constitution of a task force to support the regional crisis unit.
 - Decree of the president of the region no. 21 dated 17 March 2020 – constitution of a regional task- force to sustain the Calabria financial-productive system during the covid-19 emergency.
 - Ordinance of the president of the region no. 20 dated 27 March 2020 - further measures for the prevention and the management of the covid-19 epidemiologic emergency, ordinance pursuant to art. 32, par. 3, of regulation dated 23 December 1978, n. 833 concerning public health and hygiene: covid- 19/sars-cov-2 screening activities for health workers and monitoring of residential units.
 - Decree of the president of the region no. 25 dated 29 March 2020 – establishment of special units for assistance continuity in local health units in the provinces of the Calabria Region
 - Ordinance of the president of the region no. 20 dated 27 March 2020 - ordinance pursuant to art. 32, par. 3, of regulation dated 23 December 1978, n. 833 concerning public health and hygiene: covid- 19/sars-cov-2 screening activities for health workers and monitoring of residential units.
 - Decree of the president of the region no. 25 dated 29 March 2020 – establishment of special units for assistance continuity in local health units in the provinces of the Calabria Region.
 - Decree of the managers of the Calabria Region n°3855 dated 4 April 2020 approval of the organization of the operational group of the regional crisis unit for the covid-19 emergency as per ordinance no. 4 dated 10 March 2020.
 - Ordinance no. 35 dated 24 April 2020 “further measures for the prevention and the management of the covid-19 epidemiologic emergency, ordinance pursuant to art. 32, par. 3, of reg. dated 23 December 1978, n. 833 concerning public health and hygiene: provisions related to outpatient specialty services”.
 - Ordinance of the president of the region dated 06.05.2020, no. 40 further measures for the prevention and the management of the covid-19 epidemiologic emergency,

ordinance pursuant to art. 32, par. 3, of reg. dated 23 December 1978, n. 833 concerning public health and hygiene: provisions related to outpatient specialty services provided by public facilities.

- Ordinance no. 43 dated 17 May 2020 of the president of the Region: further measures for the prevention and the management of COVID-19 epidemiologic emergency, ordinance pursuant to art. 32 par. 3, of Reg. dated 23 December 1978, n. 833 concerning public health and hygiene.

- Ordinance no. 44 dated 18 May 2020 of the president of the region: further measures for the prevention and management of the COVID-19 epidemiologic emergency, ordinance pursuant to art. 32, par. 3, dated 23 December 1978, no. 833 concerning public health and hygiene. Even on the basis of these provisions, the Department for Health Protection of the Region has provided for the employment of health facilities and residential health facilities for the exclusive treatment of Covid-19 patients, should the regular hospital not suffice. At any rate, the Calabria region has had a 41,09% (+60) (Prime Minister office, 5 May, 2020).

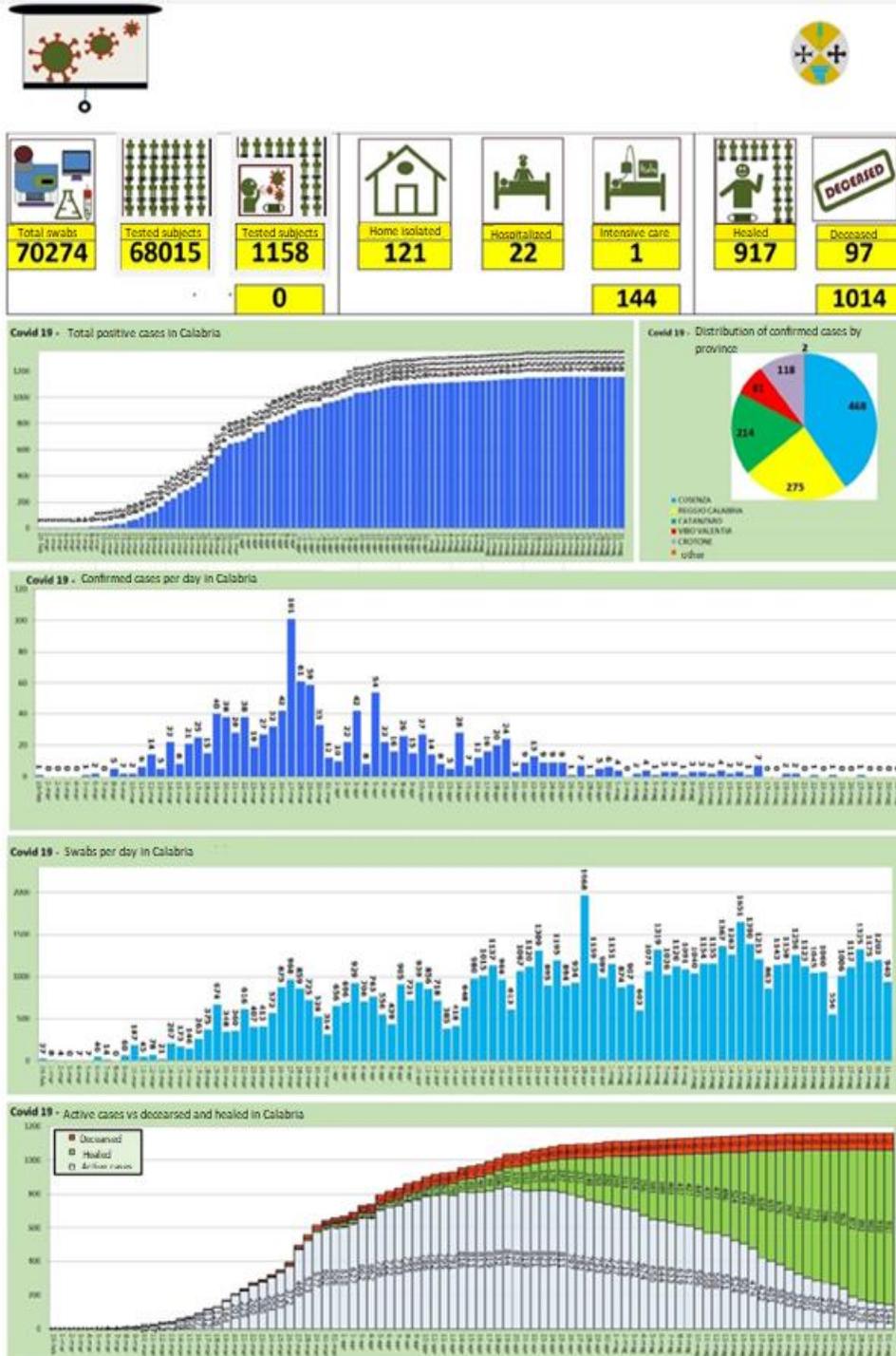
Furthermore, the region has started a an individual management of the patients who tested positive to Covid-19 through tracing, for the purpose of safety and public interest⁷, as well as an assistance, treatment and monitoring plan for the patients within the scope of the service network.

Currently, Calabria is the region with a lower weekly incidence of new cases (0,21 for 100.000 inhabitants) bringing a continuous disengagement to hospitals with a decrease of 10 hospitalized patients on a weekly basis. The region has tested 3,20% of the population and is able to provide 3,70 new tests every week for 1.000 inhabitants, with a positivity rate of 0.00 compared to the tests conducted, recording a value that is lower than all the national values. The management model has observed a moderate involvement of the territory.

The Calabria region, during “phase 2” has opted for the Hub and Spoke model in the organization of the hospital network (where regions like Basilicata, Sardegna and Sicilia, for example, have approached the dedicated COVID hospitals model). There are guidelines and other documents available for the restart of non-urgent activities.

⁷Regional platform: <https://www.rcovid19.it/mobile-app-rcovid19-regione-calabria/AppRCovid19>. The App R covid -19 of the Calabria region is created with the objective to create a map of the contagion risk, whilst providing useful and practical information to the citizens that are living their daily life in times of Covid-19.

Figure 8. COVID-19 situation, Calabria Region as of 31 May 2020.



Source: Calabria Region, Health Protection and Healthcare Policies Department - Sector 9.

5. Conclusions and Organizational Improvement Proposals

This research has analyzed, through the study of an explorative case, the tools and processes through which the Alfa Health Unit in Calabria has setup COVID Route. Thanks to the analysis of the diagnosis-treatment-assistance plan, some key issues have been identified that could be the object of specific improvement actions. Such actions can be inserted within pre-existing initiatives or projects, awarding them further structure and impulse.

For example, generally, a corporate review plan can be implemented on the so-called “hospitalization practices”, through the implementation of prevention programs on the territory, experimenting the role of the so-called “health agent”, in charge of favouring, on the territory, the contact between health services and population, acting, this way, as a “griddle” between territory and hospital, avoiding the unnecessary congestion of it. To the purpose of granting quality in terms of homogeneity of service, a standard protocol could be defined on a district level for COVID-19, the application of which could grant treatment equity in the dedicated facilities. This will make necessary to separate two specific plans, one reserved for Virus Free patients suffering from hearth diseases who need surgeries, and another reserved for patients carrying the virus. Access to COVID-free departments, operating rooms and intensive care, will be granted only after clinical evaluation, radiologic exam, virus test and negative serology to Coronavirus.

Instead, the patients that show positivity to Coronavirus and need a surgery will have to be hospitalized in a dedicated facility with biocontained rooms, where an Intensive Care unit and a dedicated operating room in strict contact with the Infectious Diseases Department will be set up. In case a patient, for whom has not yet been possible to ascertain the negativity to Coronavirus, needs an emergency or urgent surgery, the isolation procedure will have to be implemented and dedicated biocontained facilities will have to be used. This will make it possible to ensure the patients a specialty treatment in total safety for themselves, for personnel and for all the other patients.

These proposals, however, are still at a very early stage, and, coherently with the consolidating plan the Trust is going through, they will represent the application of service quality management tools, even through their integration in the corporate programming. In consideration of the complexity of the plan in place the (re)-designing of appropriate tools and organizational practices appears to be one of the directions to follow, together with the introduction of new and intense coordination mechanisms and with participation amongst various professionals responsible for the different phases.

All of the above is true even considering that the main limit of the work consists in the generalization of the results circumscribed to a research field restricted to only one Hospital Trust and limited in time. In terms of future research, further analysis

could be conducted replicating the study in other Hospital Trusts, so as to compare, and possibly generalize the results of this work.

From a critical point of view, it is to be noted that a synthetic evaluation on the completeness of the gathered data is not available; though there are some indications of it in the extended report that is published twice a week. The main limit of an information system designed this way is the time needed for the compilation of the forms; the Prevention Department of the Hospital de quo does not manage to guarantee an accurate compilation of all the fields.

A second limit stands in the difficulty to follow in time the evolution of the individual history of the disease, keeping score of possible transfers between house and hospital, between hospital departments, and also of subsequent tests conducted. The issue of the clinical state, moreover, connects to a problem of univocal definition of the adjectives used to define it, particularly in relation to the recovery, which we remember being officially defined as a negative double test, conducted, very often, many days after the clinical recovery, and for which there should be a shared definition (absence of symptoms? Recovery from pneumonia with associated state of asthenia? Absence of fever?).

It is to be noted that, to date, the recording of information regarding the domicile of patients in a social care unit, when they are dismissed from hospital with such destination, is not provided. It is preferable that this information becomes mandatory, with the domicile address in social care facilities being reported, so as to identify possible clusters.

The availability and accessibility of the information are an important aspect to consider in the planning of any type of study. In the follow-up of these patients the more simple and accessible data source is represented by conveniently linked administrative/healthcare information fluxes. However, in order to answer to many research questions, it will be necessary to provide an enrichment of these data with anamnesis and clinical information (previous and regarding a follow-up in course of operation). Regarding the choice amongst different study designs, there should not be any difficulties to be guided through traditional study models (with grafted projects, pairings, and proper sampling strategies) and more innovative solutions. These initial choices are of crucial importance and should be made after a careful evaluation and discussion amongst experts in different fields, taking into account both the aspect related to scientific objectives and interests and the availability and accessibility of the information, as well as the feasibility and the ethical implications.

5.1 Recommendations

It is suitable to suggest the following proposals:

- 1) the presence of comorbidity and the functional status must be carefully evaluated, in addition to the age. It is possible that a relatively brief course in healthy people

- may become potentially longer and, therefore, more resource-consuming on the healthcare service in case of older, frail patients with severe comorbidity;
- 2) it is to be considered the expressed previous will of the patients, through possible previous treatment provisions and, particularly, what defined (together with the doctors) from the people who are already going through the time of chronic disease through a shared simplification of the treatments;
 - 3) for patients for whom the access to an intensive care plan is deemed to be “inappropriate”, the decision to limit the treatments (s.c. ceiling of care) should be nonetheless motivated, communicated and documented. The ceiling of care placed before mechanical ventilation should not prevent lesser intensity of treatment;
 - 4) a possible inappropriateness judgment in the access to intensive care, based on distribution justice criteria (extreme imbalance between demand and availability), is justified by the extraordinary nature of the situation;
 - 5) in the decision-making process, should situations of particular difficulty and uncertainty present themselves, it could be useful to have a second opinion (even just via phone) of particularly experienced operators (for example, through the Regional Coordination Centre);
 - 6) palliative sedation in hypoxic patients with disease progression is to be considered necessary since it is an expression of good clinical practice, and it must follow the existing recommendations. Should a long agonizing period be forecasted, a transfer in a non-intensive environment must be provided;
 - 7) all of the access to intensive care must be anyway considered and communicated as Intensive Care Unit (ICU) trial and submitted, therefore, to a daily re-evaluation of their appropriateness, their treatment objectives and proportionality. In case it is believed that a patient, maybe hospitalized with borderline criteria, does not respond to the initial prolonged treatment or quickly deteriorates, a decision of “treatment desistance” and of recasting of intensive to palliative treatments, in a scenario of high patients inflow, must not be delayed;
 - 8) the decision to limit intensive treatment must be collegially discussed and shared by the attending team and – however possible- in communication with the patients (and their family), but it must be timely. It is foreseeable that the need to continuously make this type of decisions will make the decision-making process of any Intensive Care Unit better adaptable to the availability of the resources;
 - 9) the ECMO (Extra Corporeal Membrane Oxygenation) support, being it resource consuming compared to an ordinary hospitalization in Intensive Care, in conditions of extraordinary inflow of patients should be reserved to extremely selected cases and with a relatively short provision of weaning. Ideally, it should be reserved for high volume hub centres, for which a patient on ECMO absorbs, in proportion, less resources compared to what he would absorb in a centre with less expertise;
 - 10) think of the possibility to introduce the figure of the “Process Nurse” that, as the MT, follows the patients from the beginning to the end of its diagnosis-treatment plan;
 - 11) provide the employment of an algorithm for the definition of patients flows evacuate on the basis of epidemiologic and clinical criteria, and using diagnostic imaging where necessary. The combination of these elements will allow the

distinction between patients in high, medium and low COVID probability, granting, this way, the separation of the plans;

12) the relapse on the families of patients hospitalized in IT COVID-19 also must be considered, especially in cases in which the patient dies at the end of a period of total restriction of the visits.

In conclusion, the “trust” in the change plans in place has to constantly be nourished, and the management of the programming and control processes seems to be particularly important in this respect.

In the phase we are living, that is, with a system that is still under definition, the information produced by the management control tools are important for the understanding and the validation of the change processes.

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