Clinical Governance in Pandemic Times

Clinical Governance em Tempos de Pandemia

Nuno Côrte-Real¹*

* Corresponding Author/Autor Correspondente:

Nuno Côrte-Real [nuno.corte.real@hospitaldecascais.pt] Av. Brigadeiro Victor Novais Gonçalves, 2755-009 Alcabideche, Portugal

Keywords: Clinical Governance; COVID-19; Hospital Administration; Pandemics

Palavras-chave: Administração Hospitalar; COVID-19; Governança Clínica; Pandemia

Introduction

The concepts known as clinical governance are assumed as gold standard for the clinical management of health institution. For several years, the clinical leadership of Hospital de Cascais (HC) has defined its principles as the guiding framework for delivering patient care in this institution. This Philosophy has become progressively inherent to the Hospital operation.¹

COVID-19 pandemic crisis overwhelm the World Health System in a way never seen before. COVID-19 has such a huge impact in healthcare institutions and health workers that has shaken some of our beliefs and the way we feel, think and practice Medicine and this kind of shake should not pass without some reflection from our part. If we let this pass without making a profound revision and drawing the necessary conclusions, all the hard work, all the suffering and burn out of health providers will be in vain.

We can say that in times of crisis is when these principles like clinical governance are more critical to prevent the "train from falling out of tracks" but it can be difficult to implement when all resources are overrun by the attendance needs. Also, quality and patient safety (QPS) measures should still be the focus.

I will try to describe the way that we, in Hospital de Cascais have been dealing with COVID-19 pandemic and how we tried to maintain the clinical governance framework and the mind set on QPS measures.

Pandemic time frame

Before the start of the pandemic, Hospital de Cascais had a Global Transmission Disease Plan that was implemented on sanitary situations like the outbreak of Ebola in Africa or a recent outbreak of measles here in Portugal. It included an isolation room, next to the Emergency Room (ER), where a suspected or confirmed case would wait for evacuation to a designated referral unit. All the procedure was mounted to have one/two patients at a time.

By the end of January, it was clear that we were facing a sanitary crisis that would evolve to a pandemic. On January 30th, the Portuguese Health Authorities issue a general plan (nationwide) to deal with the coming crisis. It contained three phases: Preparation, Containment and Mitigation, followed by a Recovery phase. On the two initial phases all suspect cases should be referred to three Hospitals (two in Lisbon and one in Porto), so the purpose was that all suspected cases that came to ER of Hospital de Cascais, should be transfer to the referral Hospitals, so our role be only epidemiological triage.² One the same day (January 30th) WHO declared COVID-19 as a global emergency. As soon as it was sure that the COVID-19 would eventually hit Portugal, a "Crisis Cabinet" (CC) was summoned by the Hospital de Cascais Clinical Directors in which the Administration, the

Portugal, a "Crisis Cabinet" (CC) was summoned by the Hospital de Cascais Clinical Director involving the Administration, the CMO, the CNO, the COO, the Local Contagious Diseases Control Group (GCL-PPCIRA), ER Coordinators (medical and nursing), In-

1. Diretor Clínico - Hospital de Cascais Dr. José de Almeida, Cascais, Portugal.

Received/Recebido: 18/03/2021 - Accepted/Aceite: 22/03/2021 - Published/Publicado: 31/03/2021

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ternal Medicine Coordinators (medical and nursing), Support Services Management. Later on the Human Resources Service, the Occupational Health Service, Communication and Marketing and the Logistic and Infrastructures Management were included. The first meeting of this cabinet was also on January 30th.

We tried to manage this crisis using a typical crisis management protocol with a proactive phase with crisis prevention both with anticipation and defensive intension (when the critical situation is only potential e after when it becomes eminent) trying to minimize and foresee the impact of the crisis, followed by a reactive phase, immediately after the Organization is hit by the critical situation, with an offensive attitude in order to repel the situation and focus on recovery strategies.

The Crisis Management was made with three main focuses: i) Patient Safety, ii) Workers Safety, iii) compassion and humanization. We think that medicine must be patient-centered and patient safety should be our first priority but, on a crisis like this one, health provider's safety should be at the same level with no compromise. As a sanitary situation of this proportion can provoke a tendency to focus on the technical aspects, so the endeavors to maintain compassion and humanization at the center of care should be highly valued.

The first two tasks of the CC were the elaboration of two contingency plans and to promote a program of educational sessions.

The contingency plans were made with two purposes: one to define the involvement of the Hospital dealing with the pandemic and its progression depending on the needs in terms of number and severity of patients; the other one concerning the necessary changes caused by staff decrease (provoked by illness or compulsory isolation).

The Contingency Plans were structured with the following objectives:

- Compliance with normative guidelines received from the Ministry of Health, DGS (General Directorate of Health) or other regulatory bodies and recommendations by WHO and FCDC³⁻⁵:
- Defining circuits and procedures to be adopted in healthcare delivering on patients with or without suspicion of COVID-19³;
- Defining procedures that allow the continuity of the business and the Organization and Management of Services according to the resources available;
- Defining the decision-making and communication circuits.

The Staff Contingency Plan defined the progressive shut down of activities depending on the human resources available during the evolution of COVID-19 pandemic. Also identified seven key areas essential to the functioning of the Hospital:

- ER
- Intensive Care Unit (ICU)
- Operating Room (OR) one station
- Ward (depending on the demand and staff availability)

- Maternity
- Neonatology Unit
- Oncology

With the support of several other units like:

- Pharmacy
- Clinical Lab
- Sterilization
- Imaging
- · Histology Lab
- Blood bank

It was also necessary to guaranty other support activities which made the essential unit able to operate. So this contingency plan contained the minimal number of persons to keep this services running and, depending on the staff available, how much it activity would be impaired.

There were defined four levels of contingency:

- Level One all patients (suspected or confirmed) were transfer to the referral Hospital. The maximum occupancy was 4 patients at the same time. The COVID-19 patients were managed on the Global Transmission Disease Isolation Area, adjacent to the ER;
- Level Two when the Health Authority decide to stop the transfer of patients. COVID-19 dedicated area (so-called Covidarium) would be transferred to the Psychiatric out-patient clinic and ward (because it is located on an isolated area of the Hospital and the AC system is independent;
- Level Three when the capacity of the Psychiatric ward is exceeded, the COVID-19 dedicated ward is transferred to one of the wings of the Medical-Surgical Ward and the ER-Covidarium would occupy the regular ER installation (with the transfer of the "clean" ER to other facilities inside the Hospital).
- Level Four when the COVID-19 dedicated ward exceeds 75% of the in-patient capacity of the Hospital or when one of the essential units of the Hospital ceases to have the capacity to operate on minimal level. The Hospital capacity to operate would be jeopardized.

A plan was homologated on March $8^{\rm th}$, before the first case in the Hospital.

Other task of the CC was to define safe circuits, both to patients and staff, design them on paper and on the ground. There was total redrawing of the signage of the Hospital, singing out the new circuits, building hard barrier, removable partition and other architectonic structures. COVID dedicated areas were clearly signed and isolated. The CC meetings were initially twice a week (Tuesday and Friday) in February but in March and April they were held every day.

All Services develop a specific contingency plan their activity and several protocols were develop like the COVID-19 critical patient care, airway approach in COVID-19 patients, maternity approach of COVID-19 pregnant women.

Training program

The CC also launched Educational Plan that was mandatory to all healthcare personal. Initially two types of sessions were organized: i) about the virus and the disease; ii) about the correct use of PPE.

These started to be face to face but with the sanitary situation contraindicated meetings and agglomeration of people, they were available on-line. We are able to do 13 face-to-face sessions, starting on the beginning of February with an attendance of 448 persons.

Other training sessions were organized, like the airway approach on COVID-19, and a course on Intensive Care Management of this patient was recorded and available on-line.

Communication

A meeting, held daily at 10 AM, led by the CMO, with coordinators of key Hospital Services, became the main communication vehicle between the CC and the rest of the Hospital. Updates on the sanitary situation were made, as general information related with involvement of the Hospital in the combat against the disease. Also, the guidelines issued during this period were communicated and explained. This guidelines and other important information were sent to the Hospital staff by e-mail and some short indications conveyed by SMS.

The Hospital created an Internal Support Line (LAM) that could be used to clarify doubts and help on the clinical decision making. This line was managed by the GCL-PPCIRA and was operated by doctors and nurse with training on COVID-19. It was used for validation of epidemiologic suspicion, for orientation on testing policy and isolation measures, for clarifying diagnostic doubts, for help on the patient circuit and admission and implementation of guidelines.

First wave evolution

The first case of COVID-19 in Portugal was detected on March 2nd 2020 and on March 11th WHO declared COVID-19 as a pandemic. Two days after, the first patient was identified inside Hospital de Cascais. On the same day, the government declared that the country was in "Alert State". The Minister of Health orders the shutdown of all elective activity of the National Health Service on March 16th. The Hospitals were only allowed to treat urgent oncologic cases.

On March 18th the situation was upgraded to "Emergency State", the pandemic combat passed to the mitigation phase and the previous protocols with the referral of all patients to specific Hospital were cancelled, so every Hospital had to take care of all patients who sought their services.

This change of healthcare strategy was expected, and our ER Global Transmission Disease Isolation Area became insufficient. As planned, we transfer the COVID-dedicated ER to the Psychiatric Unit.

On the day after, the Rehabilitation Service (that was inactive) received the Maternity – ER and Delivery Room and all out-pa-

tient services related with obstetrics, guarantying an isolated pathway to pregnant women.

The segregate circuit to Oncology was created only on April 8th, following a specific determination of the government. Before that, the demand was not significant because cancer patients avoid trips to Hospitals. This measure was adopted as a message of safety to cancer patients, which were deeply harmed on the pandemic first times.

On March 23th, the first COVID patient was admitted on a COV-ID-dedicated Ward (the Psychiatric Ward – that had 18 beds). Two days after, we regret the first COVID related death and the next day, we had our first mechanically ventilated patient on the ICU.

By the end of the month, the demands exceed the capacity of the Psychiatric Ward and, on March 31st, the Covid-related internment was transferred to 7th floor, initially just one wing (31 beds) and, on the peak of this first wave, to both wings (62 beds) with a maximum occupancy of 50 patients.

The UCI suffer a similar expansion route with initially 6 beds devoted to COVID-19, then 12 and, on the peak, with its total capacity (18 beds) COVID-dedicated. Non-COVID critical patients were treated on the Post-Anesthetic Care Unit (PACU), which was almost inactive because surgical activity was reduced to urgent and oncology cases.

The OR had some adaptations as well. Two rooms were isolated and dedicated to COVID-19 patients, segregated circuits were design to COVID and non-COVID patients and all surgical activity without priority criteria was suspended.

On April 7th we had other first patient declared cured (considering the criteria used then) and one week later, the last contingency phase was activated on the ER and the COV-ID-dedicated area moved and occupied most of the regular ER installation (except the Observation Room) with the transfer of the non-COVID ER to the out-patient clinic, which was mostly inactive because all medical appointments (except trauma, post-operative and oncologic) were suspended.

All possible medical appointments were transformed in video or phone consultation. On May 4^{th} it was officially declared the end of mandatory total (or near total) lockdown.

From this date onwards till the end of summer, the rest of Portugal notice a residual activity of the disease, but the Metropolitan Lisbon Area registered an increase of cases during the month of June, more or less, like a second wave. This had a small impact on the National Health Service as an all, but the stresses on Lisbon Hospitals never reach a residual value.

Impact the first wave of Covid-19 on Hospital de Cascais in numbers

The way that COVID-19 pandemic impaired the Hospital de Cascais activity during the first phase of this sanitary crisis can be portrayed in numbers. These numbers refer to a period of six months from March to 31 August.

During this period, 5232 tests (RT-PCR) for COVID-19 were made, 4330 in the ER and 902 in the Wards. These tests detected 700

Positive patients, 270 were admitted, 47 of them passed in UCI (17% of the admitted patients). The average length of stay was 20 days in the wards and 12 days in the UCI. We registered 67 deaths on COVID-positive patients (25% of lethality rate), 9 of them died in the UCI (20% lethality rate).

Concerning the admitted patients, 52% were female. Forty-one patients had less than 45 years old, 65 between 45 and 64 years old, in the interval 65 to 74 we had 37 patients, the larger group (66) had 75 to 84 and 52 patients had more than 85 years old.

COVID-19 had an important impact on our staff. We made 1073 tests (RT-PCR) to Hospital de Cascais employees in the same timeframe. Till August 31st we registered 86 infected healthcare workers (43 nurses, 26 nursing assistants, 12 physicians and 5 technicians).

Risk management

Risk management is one of the main pillars of clinical governance. This includes incident reports, its clinical analysis and the design of action plans to address the improvement opportunities identified.

During pandemic times, while personal is overwhelm by the patients immediate needs, there may be a tendency to minimize the level of incident report and other tools to audit Quality on Healthcare.

During the first 6 months of the pandemic (March to August) 233 incidents were reported, with a clear decrease in April (only 18 reports) and more than 40 reports on the other months consider (the best month was March with 52 reports). Three sentinel events were reported and adequately treated with a root-cause analysis and action plan executed.

Hundred and thirty-three reports were events without damage and 20 were near miss showing that the reported events included the less severe. Comparing with 2019, in this year on the same time frame (March to August) 292 events were reported representing a decrease of 20% in 2020, especially in April with a reduction of 65%. This data can be interpreted this way: the pandemic impaired the report of events but more significantly during the peak. When the new cases incidence diminished, the reports regain the usual pace. In terms of type of events were more or less the same, with only a noticeable change: a reduction of "near misses" events (from 32% of total events in 2019 to 8% in 2020). This reduction may need further reflection. So, we can conclude that the culture to report was still active on our staff, in spite of the difficult times we experienced.

A considerable risk was identified, a risk that could jeopardize all operation. It was evident that the level of stress imposed of the frontline staff was enormous. So, a helpline was created for professionals, operated by Psychiatrist and Psychologists, in order to mitigate the effects of burn out.

Also, there was an extraordinary mobilization of the population which collected donations (food, beverage, hygiene products and even folding beds), that made the living conditions inside

the Hospital more pleasant. During the first months of the pandemic and while the Hotels were shutdown, the Hospital provided a room in some of those Hotels for the staff that was uncomfortable to go home, due to the fear of infecting the family.

Clinical effectiveness and research

As on the topic above, the need to concentrate on the patients' direct care took these topics to the bottom of the list of priorities.

We made our best efforts to contradict this tendency. On this period, the Hospital was involved on 17 observational studies, ten of them on COVID-related topics, and participated on 3 randomized control trials, one on a COVID-related topic.

The Accreditation by the Joint Commission International (JCI) is an important keystone of the quality assessment of the hospital. We had several Accreditation processes and audits, and the grant has been regularly assigned.

We have a mandatory annual audit to confirm the compliance of the hospital to the JCI standards. Even under the effect of this pandemic, we received the JCI focal audit in September 2020 and, in spite of the difficult times experienced, we improved our level of compliance compared with the 2019 audit.

Clinical audit

A Clinical Audit was carried out to evaluate the approach to the pandemic. The results were presented in September and the highlights are as follow:

The strategy for preparing the hospital response to the COV-ID-19 pandemic followed the recommendations of the Centers for Disease Control and Prevention (CDC) and European Centers for Disease Prevention and Control (ECDC) and of the Direção Geral da Saúde (DGS), and in general it effectively fulfilled the requirements required in the areas of planning and decision-making, in the preparation of a written action plan and its communication, and in the execution of the elements of the action plan proposed.

Planning and decision-making structure

A crisis cabinet was created that design a plan which was fully aligned with the national strategic plan and complied with the laws of the national state of emergency.

The recommendations of the CDC and the European Center suggest that this team be expanded, including a more diversified clinical panel with pediatricians and ICU. Occupational Health and Human Resources should be included in the planning structure of the hospital response. The high number of infected professionals may be related with this.

Elaboration of a written action plan and its communication

There is a very complete action plan, generated by the Crisis Cabinet where the tasks to be executed are outlined. The dissemination of procedures and strategy was not particularly effective, especially with regard to the timing of the disposal to the professionals. The internal communication of Cascais Hospital had a spokesperson, the Clinical Director. For internal communication, the hospital used all the means and channels available at the institution: intranet, screens, e-mails, which were adapted to each event.

To reinforce internal communication, an Internal Medical Support Line (LAM) was created and used temporarily to clarify doubts and help in decision-making. However, the disclosure and access to detailed information on the action plan and protocols had the limitations, especially because health professionals who work at the patient's bedside do not have time or physical conditions to consult platforms and emails.

Implementation of the elements of the action plan

In relation to PPE usage rules, there were some confounding factors in the first rule in March at the beginning. A later revision of the protocols made it clearer and more adjusted, complying with international recommendations. Nevertheless, it is difficult to monitor the correct use of PPE by the professionals. In addition to the peer control, there should have been organized an audit to verify the correct use of PPE or the need for more training.

Therapeutic approach

From a clinical point of view, there is clarity in the flowchart for approaching and guiding the suspected or confirmed COVID patient from entry to discharge. A guide for the caregiver or infected person was even prepared with information on how to proceed at home. We identified two action protocols that deserve reflection/review, the ICU admission criteria and the COVID patient approach protocol for cardiorespiratory arrest. In terms of hospital mortality, Hospital de Cascais do not differ significantly from those in the literature except for one point: Hospital de Cascais we have a higher mortality rate in the Wards than in the ICU, which was not the case in the majority of cases.

Summary

The Audit concluded that, in general terms, the response of the Hospital was adequate and in-line with major guidelines. Nevertheless, some improvement opportunities were detected. For instance:

- · Communication should have been better;
- There should have been more clinical engagement in the Crisis Cabinet;
- The use of PPE should have been more clear from the beginning;
- Some specific protocols need some reflection.

Conclusion

Dealing with this sanitary crisis, undoubtedly the worst situation faced by the Healthcare System in modern years, has been a very intense challenge. The level of stress imposed to the Hospitals, to the Regional Administration, to National Health Authorities was an ordeal.

The effect of this conjuncture on people was enormous, with levels of burn out never seen before. The impact on hospital management put in risk all the operation. Hospitals were recently on the verge of collapse. Clear leadership, precise guidelines and personal commitment were fundamental for the management of this crisis. The cornerstones of clinical governance may be also a tool to maintain the Hospital on tract even in extremely difficult times.

But the most important asset to overcome this situation is people. It was clearly noticeable on the way that Hospital de Cascais deal with the first phase of the COVID-19 pandemic that the spirit of the hospital staff was fundamental. People closed ranks, united themselves, face the crisis will a real team spirit, gave all that it had to the patients and the Hospital, went beyond the call of duty. Hospital de Cascais has a team that can be proud of the extraordinary achievement accomplished.

Responsabilidades Éticas

Conflitos de Interesse: Os autores declaram não possuir conflitos de interesse.

Suporte Financeiro: O presente trabalho não foi suportado por nenhum subsídio ou bolsa.

Proveniência e Revisão por Pares: Comissionado; sem revisão externa por pares.

Ethical Disclosures

Conflicts of Interest: The authors have no conflicts of interest to declare.

Financial Support: This work has not received any contribution grant or scholarship.

Provenance and Peer Review: Commissioned; without external peer review.

ORCID iD: Nuno Côrte-Real https://orcid.org/0000-0002-0738-3361

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