



ORIGINAL ARTICLE

An original logigramme to make safe discharge and community reintegration for COVID-19 patients

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Keywords

COVID-19 • Safe discharge • Community reintegration criteria

Summary

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is the microorganism responsible for the aggressive Coronavirus Disease (COVID-19) pandemic. During the such pandemic, discharge and community reintegration of patients are critical phases in guaranteeing public health. A review of the international and Italian experiences that represent the best available evidence was carried out, mainly focusing on the precise allocation of tasks and related responsibilities. The report provides a proposal for a systematic management pathway dedicated to COVID-19 patients. The original result is a logigramme to guide health practitioners on discharge and community reintegration of COVID-19 patients.

To standardize clinical attitudes helps in ensuring quality of care and patient safety, should be a core element even during a public health emergency. The logigramme suggests, after discharge, 14 days of further isolation with regular health monitoring and, finally, the execution of a nasopharyngeal swab for identification of SARS-CoV-2 viral RNA. Home-cared patients should be placed on 7 days of further isolation after at least 2 negative RT-PCR tests for respiratory tract samples (nasopharyngeal swab). The logigramme is already used in the Department of Prevention - Local Health Agency of Lecce (Apulia) but it will be updated according to the latest research findings.

Introduction

On January 30th 2020, the WHO declared the international outbreak of the new coronavirus SARS-CoV-2 as a public health emergency of international concern, as provided for in the international health regulation of 2005 [1]. The Severe Acute Respiratory Syndrome (SARS) is known to be a “High Consequence Infectious Disease (HCID)” also called Infectious Disease of High Consequence (IDHC), i.e. a disease which poses a significant threat to human health. Patients affected by such diseases usually develop severe symptoms and require a high level of assistance with death rates that may be quite high [2]. The Apulia Region, starting from January 31st, under a decree from the Ministry of Health, established a regional Task Force for the management of the infectious outbreak; the Task Force arranged the “Operational protocol for the management of suspected COVID-19 cases in Apulia” and, after the cases reported in Lombardy and Veneto, the “COVID-19 Operational plan, Apulia Region”. By the Order of the Regional Government No 172, dated 6 March 2020, within the meaning of Article 11 of D. Lgs. No 1/2018 and to transpose the Measures provided for in the Document *Civil protection operational measures for the management of the epidemiological outbreak of COVID-19* as referred to in the note of the Head of Civil Protection Department – Coordinator of OCDPC Interventions No. 630/2020 prot. n. COVID/001656 of 3 March 2020, the regional Crisis Unit is established to take actions and measures, as specifically identified in the above-mentioned Document [3].

The scenario of the clinical condition of patients at national level is influenced by the fact that it has not yet been classified in all Regions and Autonomous Provinces in a standardised manner in accordance with the provisions of COVID-19 Surveillance, since the structured processing of such data is still under preparation. The assessment provided by the Italian Institute of Health updated to April 2nd reported that the clinical condition was available only for 39,884 cases, of which 2,360 (5.9%) asymptomatic, 5,587 (14.0%) paucisymptomatic, 5,155 (12.9%) with symptoms whose severity level was not specified, 17,085 (42.9%) with mild symptoms, 8,494 (21.3%) with severe symptoms requiring hospitalisation, 1,203 (3%) with clinical picture of critical illness requiring hospitalisation in Intensive Care Units [4].

From Apulia epidemiological bulletin, updated to 7 April 2020 [5], it was found that out of 2,514 confirmed cases, 938 were in isolation (known in 1,646 cases), 708 hospitalized (known in 1,646 cases), 209 deceased (known in 1,779 cases) and 168 recovered (known in 1,779 cases). According to the recent literature, the clinical process evolution of hospitalized patients has shown that 10-20% of patients are hospitalized in a RICU (Respiratory Intensive Care Unit), 3-10% are intubated, 2-5% died [6].

The number of hospitalized patients in Apulia (which “in large percentage” are the potential patients to be discharged) is the reason because of we have developed a dedicated project-pathway. It is an original organizational model for improving patient safety and quality care inside and outside the hospital.

Actually, as recommended by ECDC (European Center for Disease Prevention and Control), we answered to a strategic clinical governance requirement: define the “state of discharge” of patients according to the “checklist for the designated treatment facility for HCID case (s)” [2].

Purpose and objectives

The mission of the National – and therefore Regional – Healthcare System is to guarantee a “fair and appropriate” quality of healthcare. The review of the discharge letters of COVID-19 patients from hospital units showed the presence of a widely diversified de-hospitalization attitude: in case of discharge as a consequence of two negative swabs as recommended by Italian Ministry of Health [7] or with one negative swab and one unknown, it is recommended a 14-days long fiduciary isolation, whose follow-up is entrusted to general medicine doctors; instead, in other cases, it is simply recommended observing common precautionary measures.

It is necessary to standardize the COVID-19 patients discharge from the hospital, in order to have both a systemic (shared at a regional level) and a systematic perspective and to ensure the healthcare safety.

The final objective of this work is to assess, promote and spread guidelines dedicated to the management of COVID-19 patients, home-cared or hospitalized ones (from hospital discharge to community reintegration).

These guidelines have been developed and calibrated based on currently available national and international experiences and best evidences. We have developed a procedure to be used as a decision support for all Healthcare Professionals involved in the COVID-19 care system (home cared patients and hospitalized ones).

This procedure could be reviewed in accordance with progressive scientific updates.

Focus on RT-PCR test performed using swabs

The most commonly used and reliable test for diagnosis of COVID-19 has been the RT-PCR test performed using nasopharyngeal swabs or other upper respiratory tract specimens, including throat swab or, more recently, saliva. In most individuals with symptomatic COVID-19 infection, viral RNA in the nasopharyngeal swab as measured by the cycle threshold (Ct) becomes detectable as early as day 1 of symptoms and peaks within the first week of symptoms onset. Positivity starts to decline by week 3 and subsequently becomes undetectable.

The virus persists longer with higher load and peaks later in the respiratory tissue of patients with severe disease and the duration of the virus was significantly longer in men than in women, and significantly longer in patients older than 60 years than younger ones [8].

In some cases, viral RNA has been detected by RT-PCR even beyond week 6 after the first positive test. A few

cases have also been reported positive after 2 consecutive negative PCR tests performed 24 hours apart [9].

The evidence of the extrapulmonary detection of viral RNA in both symptomatic and asymptomatic subjects is an interesting element from a clinical and epidemiological point of view.

Zou et al. 2020 report that the viral load of asymptomatic patients was similar to symptomatic ones, indicating a transmission potential of asymptomatic or pre-symptomatic patients. The study reports that patients with few or no symptoms had modest levels of detectable viral RNA in the oropharynx for at least 5 days [10].

However, we know that a positive PCR outcome reflects only the detection of viral RNA and does not necessarily indicate presence of viable virus [11].

Further studies, such as culture of SARS-CoV-2, should be carried out to investigate the actual potential infectiousness.

It has been reported that several cases recovered from COVID-19 tested positive for SARS-CoV-2 after discharge (re-detectable positive, RP) but the clinical characteristics, significance and potential cause of RP patients remained unknown [12].

Four patients with COVID-19 who met criteria for hospital discharge or discontinuation of quarantine in China (absence of clinical symptoms and radiological abnormalities and 2 negative RT-PCR test results) had positive RT-PCR test results 5 to 13 days later [13].

In literature there is also a study regarding the case of an asymptomatic discharged patient with SARS-CoV-2 nucleic acid retested positive. Although no scientific evidence demonstrated that a discharged patient who had repeated SARS-CoV-2 nucleic acid positive could be infectious to others, these clinical experiences after discharge arouse concern regarding the present discharge standard of COVID-19 [14].

All these evidences justify the need for particular attention in management during the community reintegration of COVID-19 patients to protect public health.

International review of COVID-19 patients discharge

In order to discharge clinically recovered patients, the WHO, CDC and ECDC recommend the collecting of two respiratory swabs at least 24 hours apart from each other [15-17].

The ECDC reports that, current criteria for discharge COVID-19 patient include both resolution of symptoms and laboratory evidence of SARS-CoV-2 clearance from the upper respiratory tract. Criteria should be reviewed according to the local context [18]. The current international criteria for discharge are summarised in the table written by ECDC [17].

According to some scientifically tested references, under unspecified conditions (“if suitable”) home care could be performed in symptomatic patients who no longer require hospitalization [19].

On March 24th the CDC clarified that, when clinically indicated, COVID-19 patient can be discharged from a health care facility. For such patients, a discharge does not require that they meet CDC criteria for the discontinuation of COVID-19 transmission-based precautions (TBP) [20].

CDC guidelines provide a possible dual “destination” for discharged COVID-19 patients. For the patient discharged home the discharging facility should consider the home’s suitability for assuring patient’s isolation and patient’s ability to adhere to home isolation recommendations. Isolation should be maintained at home if the patient returns home before discontinuation of TBP.

For the patients discharged to Long-term Care (LTC) or Assisted Living Facilities there are three possible scenarios:

1. when TBPs are still required transferred COVID-19 patients should go to a facility with adequate personal protective equipment and an ability to adhere to infection prevention and control recommendations for the care of COVID-19 patients. Preferably, the patient would be placed at a facility that has already cared for COVID-19 cases, in a specific unit designated to care for COVID-19 residents;
2. transferred COVID-19 patients for whom TBPs have been discontinued but continue to have persistent symptoms of COVID-19 (e.g., a persistent cough) should be placed in a single room and be restricted to their room;
3. transferred COVID-19 patients for whom TBPs have been discontinued and the symptoms have resolved do not require further restrictions.

ECDC technical report suggests criteria to be considered when deciding whether a confirmed COVID-19 case can be safely discharged from hospital or released from home isolation: the most important factors are the existing capacity of the healthcare system, laboratory diagnostic resources, and the ongoing epidemiological situation.

“COVID-19 patients may be discharged from hospital and moved to home care (or other types of non-hospital care and isolation structures) based on:

- clinical criteria: e.g. no fever for > 3 days, improved respiratory symptoms, pulmonary imaging showing obvious absorption of inflammation, no hospital care needed for other pathology, clinician assessment;
- laboratory evidence of SARS-CoV-2 clearance in respiratory samples;
- 2 to 4 negative RT-PCR tests for respiratory tract samples: nasopharynx and throat swabs with sampling interval ≥ 24 hours. Testing at a minimum of 7 days after the first positive RT-PCR test is recommended for patients that clinically improve earlier;
- serology: appearance of specific IgG when an appropriate serological test is available”.

The scientific report suggests, after discharge, 14 further days of isolation with regular health monitoring (e.g. follow-up visits, phone calls) if, and only if, the patient’s home is equipped for patient isolation and the patient takes all necessary precautions that we call “self-control” (e.g. single room with good ventilation, face-mask,

reduced close contact with family members, separate meals, good hand sanitation, no outdoor activities) in order to prevent further spread of SARS-CoV-2 and to guarantee public health [17].

The Ministry of Health and Family Welfare, Government of the People’s Republic of Bangladesh proposed a “Revised Discharge Policy for COVID-19” and the classification of the patients based on clinical severity: mild/very mild/pre-symptomatic cases; moderate cases admitted to dedicated COVID Health Centre (Oxygen beds); severe cases including immunocompromised (HIV patients, transplant recipients, malignancy). Only for the last two categories RT-PCR test is required before discharge [21].

National and regional contextualization: Lecce’s clinical pathway for hospital discharge and community reintegration

By now, in the existing procedures for the management of hospital discharge in Italy (in particular in Veneto [22] and Liguria [23]) the presence or absence of symptoms or clinical recovery is considered a critical element in the decision-making procedure.

Tuscany [24] has developed some guidelines to manage the path of the COVID-19 patients inside and outside the hospital. These guidelines are considered valid and shareable since the positivity/negativity of the nasopharyngeal swab is considered fundamental.

Unless there are conditions of absolute unavailability to adopt laboratory support, it is considered essential to use a “test-based strategy” focused on the execution of the pre-discharge Nose-Pharyngeal swab. SARS-CoV-2 RNA is isolated in only 32% of Oropharyngeal Swabs (OP), which is significantly lower if compared to 63% of Nasopharyngeal Swabs (NP) [25].

The positive RNA amount reaches the target peak 7-10 days after the onset of symptoms in the upper respiratory tract specimens and subsequently it decreases constantly, while in the lower respiratory tract specimen it remains higher for 3 weeks after the onset of the disease [26].

WHO [27] and CTS (Italian scientific and technical committee) [28] recommend using NP as standard diagnostic approach.

Based on the research of international and national sources, the following step-by-step pathway dedicated to the COVID-19 patient during hospital de-escalation and discharge is proposed.

For hospital de-escalation of patients who no longer need (clinical criterion) assistance in Intensive Care, it is expected that:

1. if positivity to SARS-CoV-2 persists (ascertained with a positive result for the presence of SARS-CoV-2 in NP swabs) but clinical stabilization exists (ordinary definition criteria), it is expected transferring to a COVID-19 normal block hospitalization;
2. if negative for SARS-CoV-2 (ascertained with a negative result for the presence of SARS-CoV-2 in 2 NP swabs collected at least 24 hours apart) but in

need of medical assistance, it is required transferring to a NO COVID-19 ordinary hospitalization block;

3. if prolonged respiratory assistance is needed, it is required: respiratory rehabilitation in a structure with a dedicated COVID-19 area in case of persistence of SARS-CoV-2 positivity (ascertained with a positive result for the presence of SARS-CoV-2 in NP-swabs); or respiratory rehabilitation in a NON COVID-19 structure in case of persistence of SARS-CoV-2 negativity (ascertained with a negative result due to the presence of SARS-CoV-2 in 2 NP-swabs collected at least 24 hours apart).

The development of a set of clinical indicators of “clinical stabilization” is based on the statistical evaluation of the frequency of evidence of the signs related to the symptoms presented by COVID-19 patients:

1. anosmia and ageusia seem to be part of important symptoms and clues for the diagnosis of COVID-19, mostly in the early stage of the disease [29, 30];
2. fever often present with non-constant frequency in different cohorts of patients. Despite this COVID-19 cannot be excluded, even if fever is not present;
3. gastrointestinal symptoms, about 10% of patients develop gastrointestinal symptoms (nausea and/or diarrhoea), before the insurgence of fever and dyspnoea [31];
4. silent hypoxia. In particular elderly can develop hypoxia even in absence of dyspnoea symptoms [32].

Recent studies report that COVID-19 could present a broader clinical spectrum characterized by the absence of any symptoms to heart, digestive tract or Ear-Nose-Throat (including anosmia and ageusia) manifestations and by the presence of peculiar skin manifestations [33]. Physical examination is usually non-specific [6].

Discharge criteria (clinical + test-based) proposed by Toscana Region [24] that are considered as sharable are the following:

1. at least 48 hours of apyrexia;
2. saturation level $\geq 94\%$ ($\geq 90\%$ for chronic patients) in ambient air from at least 48 hours or P/F ($\text{PaO}_2/\text{FiO}_2$) in ambient air > 300 from at least 48 hours RR (Respiratory Rate) < 22 at rest;
3. two negative nasopharyngeal swabs collected 24 hours apart and negative test for SARS-CoV-2 before hospital discharge.

Such criteria have to be fulfilled in order to proceed with the next steps of the clinical path dedicated to the patient who required hospitalization for COVID-19 treatment.

The logigramme: a community reintegration protocol for COVID-19 patients

We reported the protocol we have developed and already applied (Figs. 1, 2):

- *If the patient's discharge to his own home is possible:*
 1. hospital doctor suggests home isolation for 14 days;

2. hospital doctor sends the discharge letter to DPHCM (Department of Public Health and Community Medicine). The letter specifies that home isolation is suggested and also clarify that the follow-up will be managed by the GP (General Practitioner);
3. the DPHCM requires that COVID-19 patients have to self-isolate at home, following the already existing operating modes prior to evaluation with NP swab in case of symptomatic patients, at the end of the isolation period.

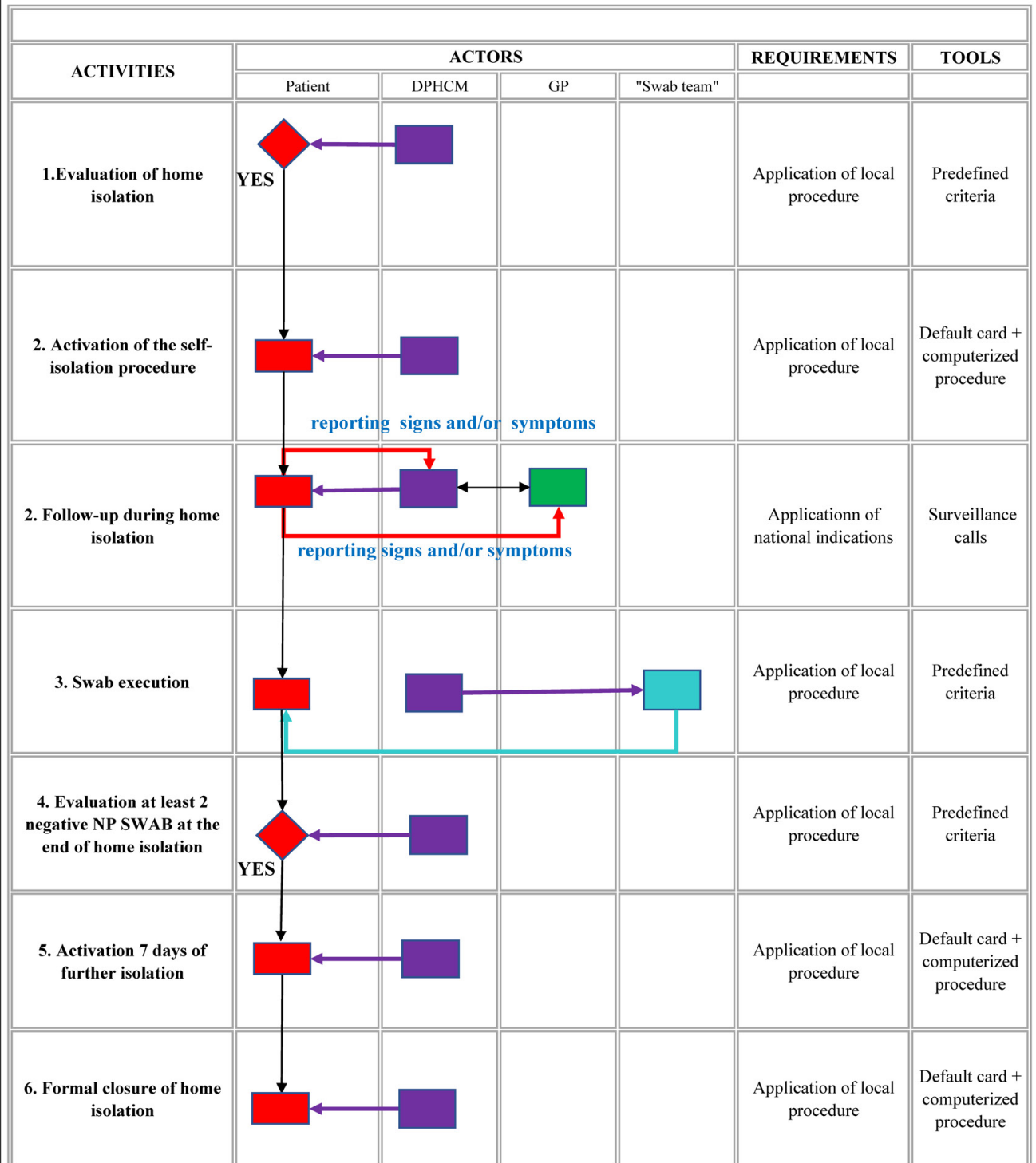
During the follow-up the communication between GP e DPHCM is constantly guaranteed.

- *In case of patient discharge at long-term care facility:*
 1. the hospital doctor suggests home isolation for further 14 days under the control of the long-term care facility. As specified in a local document Apulia's document [34] it's necessary to provide that the facility satisfies technical-logistic-structural requirements;
 2. hospital doctor sends the discharge letter at DPHCM; the letter explicit that home isolation is required and that the DPHCM is responsible for the follow-up phase (also specifies the fields of competence and clinical management dependent on the GP);
 3. the DPHCM requires that COVID-19 patients have to self-isolate at home, following the already existing operating modes prior to evaluation with NP swab in case of symptomatic patients, at the end of the isolation period.

During the follow-up the communication between GP, long-term care facility and DPHCM is constantly guaranteed.

- *Lastly, for the patient that did not need hospitalization and that has been managed at his own home, community reintegration follows the process as below:*
 1. DPHCM makes the decision of the home isolation up to clinical resolution, following the already existing operating modes;
 2. DPHCM is responsible for the follow-up during the home isolation period, as indicated by ministry guidelines;
 3. the patients, during the follow-up communicate to the GP and DPHCM the insurgence of symptoms for the fulfilments of respective competences;
 4. DPHCM orders the execution of NP swab following the pre-set criteria (14 days after the first day of isolation and 7 days after the first day in absence of symptoms);
 5. DPHCM activates 7 further days of home isolation after at least 2 negative RT-PCR tests for respiratory tract sample (NP swab);
 6. DPHCM requires that COVID-19 patients have to self-isolate at home, following the already existing operating modes, after 7 days from the result of two consecutive negative SARS-CoV-2 NP swabs (collected 24 hours apart).

Fig. 1. Logigramme to safe community reintegration for home cared COVID-19 patient.

**Legend: the meaning of the geometrical shapes**

Rectangle: activity to be performed and the related responsibility

Rhombus: choice to make/decision to be taken

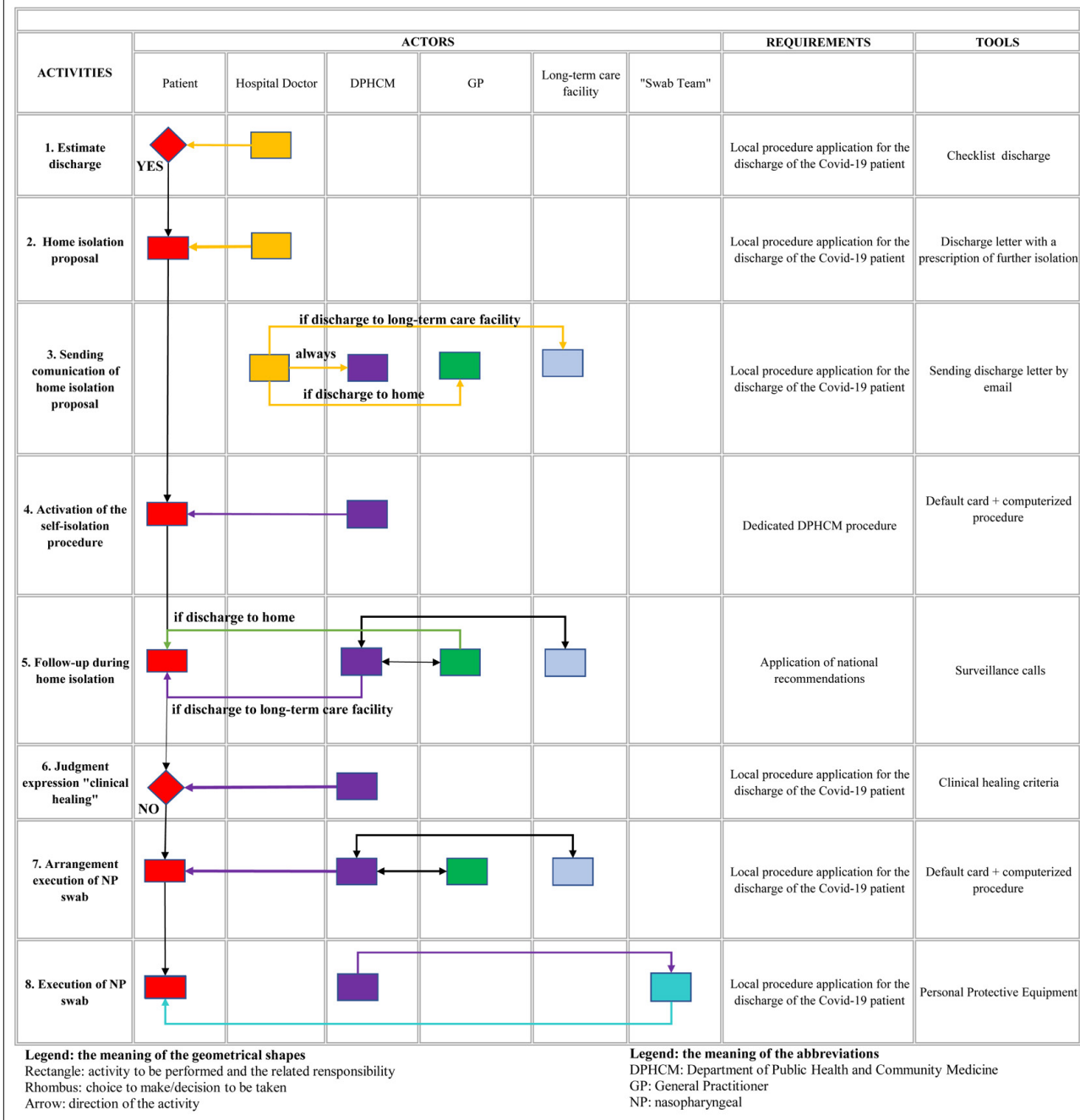
Arrow: direction of the activity

Legend: the meaning of the abbreviations

DPHCM: Department of Public Health and Community Medicine

GP: General Practitioner

NP: nasopharyngeal

Fig. 2. Logigramme to safe discharge and community reintegration for hospitalized COVID-19 patient.

The present pathway could be implemented by integrating the serological tests that are now available: they are fundamental in finding the virus and for conducting the epidemiologic evaluation of viral diffusion, but as OMS recommends [35] further evidence is needed about their performances and operational utility before their use for the SARS-CoV-2 diagnosis [36].

Conclusions

Since COVID-19 is a novel disease, guidance by scientific and globally shared evidence is often unavailable: it is necessary to urge and promote standardized behavior.

We potentially provide a practical and feasible solution to satisfy the need for an optimal community reintegration for COVID-19 patients.

The leading idea is sharing a tool of COVID-19 patients management, overcoming certain limitations that have conditioned the present care system.

The logigramme based on a systematic review is already used in our local area: step by step it explains what we do and how we do it.

The punctual and rigorous description of tasks and related responsibilities should have significant impact on single patient's outcome and public health too.

The real effects of logigramme implementation will be studied and analyzed in the second phase of our study

according to the outcome of ongoing studies about viral clearance.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

FD and AF conceived the study and drafted the manuscript. All authors revised the manuscript and performed a search of the literature. All authors have read and approved the latest version of the paper for publication.

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