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# **Interim provisions on telemedicine healthcare services during COVID-19 health emergency**

Version of April 13, 2020



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Version April 13, 2020

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Istituto Superiore di Sanità

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The document provides support for the realization of services in Telemedicine during a COVID-19 emergency, offering indications, identifying operational problems and proposing solutions supported by evidence, but also easily dispensable in practice. The indications are collected for simplicity in a single reference model but can be used in various combinations to provide health services and psychological support, to proactively monitor the health conditions of people in quarantine, in isolation or after discharge from the hospital, or isolated at home from the rules of social distancing but in need of continuity of care, even if they are not COVID-19 infected.

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## Target audience

This report is geared primarily to healthcare professionals and managers involved in COVID-19 emergency.

## Glossary of terms

<b>GP</b>	General Practitioner
<b>PHR</b>	Patient Health Record
<b>PGP</b>	Pediatric General Practitioner
<b>SSN</b>	<i>Servizio Sanitario Nazionale</i> Italian National Health Service

# Introduction

The National Centre for Telemedicine and New Healthcare Technologies of the Istituto Superiore di Sanità (ISS, the National Institute of Health in Italy) is collaborating with the operating realities on the Italian territory, since the beginning of the national emergency from COVID-19, providing its support to the realization of concrete and rapid solutions to be applied and which comply with current regulations and such as to offer the best guarantees of health safety for both patients and professionals.

There are numerous needs for care and assistance both in hospitals and even more in the territories. Besides, especially in the field of primary care, doctors solicit interventions that are easy and quick to apply, which have a pragmatic technological and organizational approach but are also rigorous in terms of medical practice and safety protection, covering real demands, even non-local, with scalable solutions as needed and using the network to cancel the distance between people and create insurmountable barriers for the virus (1, 2).

On March 4<sup>th</sup>, 2020 at the ISS scientific meeting (weekly briefing online to share scientific information against COVID-19), the National Centre proposed, a first operating model designed to obtain an active telemedicine service in the most affected territories in a few days with the idea of quickly covering, for a limited period, the needs due to quarantine of large areas.

From this initial idea, given the rapid evolution towards the pandemic (3, 4) and the prospect of having to face a long period of social distancing (5, 6), this work was developed to provide those who are organizing telemedicine services with a reference model that facilitates their implementation in this particular period. It is a document based on the identification of practical problems and the proposition of solutions scientifically supported by the evidence, but also easily adoptable in clinical and care practice.

This work was designed for the situation of health emergency in relation to the spread of COVID-19 and consequently the possibility of extending the telemedicine services activated during this emergency beyond the duration of the same is not studied. The reason for this lies in the fact that at present, with regard to the Italian public health system with its almost unique characteristics, a further in-depth analysis from a health and management point of view is needed concerning on the methodology for evaluating telemedicine services. They must be consistent with each other throughout the national territory, but also adaptable to local realities, in order to obtain their lasting stabilization in practice.

The indications illustrated here are collected in a single reference model, for simplicity of presentation. This model is designed to offer health services and psychological support to people at home using telemedicine solutions, in order to proactively monitor their health conditions, both after hospital discharge, during quarantine or isolation, and in case of home isolation induced by the rules of social distancing for those specific categories of people who need continuity of care, even if they are not infected.

## Addressable home care needs in telemedicine during COVID-19

In the COVID-19 health emergency, the Italian National Health Service (*Servizio Sanitario Nazionale*, SSN) is called upon to provide services to persons in quarantine or in solitary confinement with unprecedented significant numbers. These services have the dual purpose of helping to combat the spread of COVID-19 and also to ensure as far as possible the continuity of care and assistance to which people are entitled. Moreover, even those who find themselves effectively isolated from their home as result of the necessary rules of social distancing may still need continuity of care and assistance (7-9).

Therefore, although it is a priority to increase the possibilities of home care for people with COVID-19 for the reasons just mentioned and at the same time, the need for care and home care cannot be overlooked for those people who need it cause of their pathological conditions or frailty. Besides, all these needs must be address to emergency health conditions, with a relative lack of material and human resources and taking care to observe the anti-contagion rules for the greatest possible protection also for health personnel.

The use of remote services is therefore fully justified. They should be provided to people, where possible, primarily through modern digital and telecommunication technologies, which offer the best operational opportunities compared to the use of previous technologies. The services that can be activated in telemedicine are manifold where they were in operating conditions before COVID-19 (10, 11). Otherwise, where telemedicine is not yet structured in a system of national significance, being in the emergency health situation, it is necessary first of all to create and make available those solutions that can be activated quickly, in a few days, that can be used by people at home with the technological equipment available to them immediately and which can be activated for periods appropriate to the needs of the emergency. Based on the Chinese experience of the evolution of the epidemic, in first approximation, these services must guarantee the activity for no less than 90 days and it is strongly advisable to provide for an extension procedure in case of further needs related to the possible persistence of the health emergency (12).

In realizing remote services, it is necessary to keep in mind the relational needs of users with the health system. Thus, isolation within one's home makes it particularly desirable to rely on a service that can be easily used remotely, being able to quickly access the conversation with the health workers, as needed. Due to the limitation of travel, people expect to receive the solution of their problem through telematic contact, or a clear indication of how to solve it or at least to perceive the real possibility of being assisted effectively and safely in any case. In the absence of the aforementioned findings, the person will tend not to trust the proposed system and not to use it, especially when he is faced with pressing needs. In reality, these interactions between the person and the operators are present in any assistance service, but at a distance, they are amplified by the awareness that the healthcare provider is actually far away and that it is achieved by a technology that the user can use but usually don't dominate.

In addition to the above considerations, it is essential to structure the remote service based on the differences in the possible situations of use, which in turn depend on the type of recipients of the home service (13). In the COVID-19 health emergency, following the case definitions in the C.M. 0006360 of 02/27/2020, four types of people (14) have been identified by the ISS (14) who, due to their isolation, require health checks at the home:

- 1) asymptomatic people who have come into contact with a positive COVID-19 case (quarantine up to 14 days from the last contact with the case);
- 2) paucisymptomatic people who came into contact with a positive COVID-19 case, but having a negative COVID-19 test (isolation up to 14 days from the last contact with the case);

- 3) paucisymptomatic people with positive COVID-19 test (isolation until test negativization and disappearance of symptoms);
- 4) patients discharged from the hospital clinically cured but still COVID-19 positive.

This list was designed to keep people who have become infected or suspected of being under health control, based on current knowledge about the new SARS-Cov-2 coronavirus, to combat the spread of the infection and to monitor any aggravations clinics related to viral disease. These contrasting activities can be carried out by health services that operate in telemedicine, monitoring at home the evolution of the state of health of the asymptomatic persons and of the clinical picture of subjects who have mild or moderate symptoms of COVID-19, making it possible to maximize the possibility of contagion control even in situations where the quantity of positivity tests for COVID-19 is insufficient and in any case contributing to mitigate any health system difficulties.

However, the care outcomes that are possible with telemedicine, in all its different practical forms, albeit in less than optimal conditions due to the emergency, are wider and include remote control of medical-surgical treatments in multiple clinical situations. (15-19).

For this reason, in affirming that telemedicine represents a concrete, feasible and safe option for home control of all the four types listed above, it seems appropriate to indicate also a further typology of people towards whom to direct telemedicine services during COVID-19 emergency:

- 5) patients suffering from chronic diseases or requiring long-term treatments, which are normally managed in part or whole by territorial services or by residential structures (just think by way of example: diabetes, chronic cardiovascular diseases, COPD, pain therapies, chemotherapies, psychiatric diseases, disabilities), also including people suffering from rare diseases and frailty conditions that require constant contacts with the health structures and the reference health workers, or people who need special non-hospital but non-deferrable assistance and/or support (for example pregnant women, new mother or people with psychological problems).

These people may also fall into one of the cases or close contact definitions listed in the C.M. 0007922 of 09/03/2020 - annex 1 (which constitutes an update of the previous C.M. 0006360 mentioned above).

It should be made clear that telemedicine should not be used to try to perform medical treatments at home on people with serious illnesses who require intensive hospital care instead.

Concerning remote telemedicine services, to optimize resources, it is convenient to reduce the previous division, without contradicting it, to the following scheme with just three typical situations:

<b>Situation A</b>	Persons <u>not</u> affected by pathologies before the time when quarantine or isolation was required, asymptomatic, and who fall under the definition of close contact or confirmed case (C.M. 0007922 – 09/03/2020).
<b>Situation B</b>	Persons <u>not</u> affected by pathologies before the time when isolation was needed, who exhibit mild to moderate symptoms compatible with COVID-19 infection and who fall under one of the definitions of suspected, probable, or confirmed cases (C.M. 0007922 – 09/03/2020).
<b>Situation C</b>	People suffering from chronic diseases, rare diseases and people in conditions of frailty, or who require long-term treatments or special non-hospital care and/or support, and who need to maintain the continuity of services during quarantine, isolation or during the period of application of the social distancing rules.

## **A. Persons not affected by pathologies before the time when quarantine or isolation was required, asymptomatic, and who fall under the definition of close contact or confirmed case (C.M. 0007922 – 09/03/2020).**

In this situation, we find those people who are indicated in types 1 and 4 of the ISS Working Group on Infection Prevention and Control (see above) (12). For them, only the health check of the state of health is necessary to record the possible appearance of symptoms, verifying and supporting the adherence of individuals to the hygiene and behavioural rules aimed at contrasting the spread of viral contagion.

There are four main needs for these people that can be met remotely:

- A(1) the measured verification of the evolution of the physical state regarding possible contagion, during the whole necessary period, to grasp the possible appearance of signs and symptoms of coronavirus;
- A(2) the possibility of requesting general information or hygiene-behavioural interviews to reduce the risk of coronavirus infection;
- A(3) the possibility of requesting psychological support to alleviate the inconvenience of the restriction of freedom and interpersonal contacts;
- A(4) the possibility of requesting an interview with the GP/PLS for the usual activities of territorial medical assistance, with particular reference to the possibility of obtaining any prescriptions or certifications.

The people who, being in this situation (A), develop symptoms, mild or moderate, suspicious for COVID-19, change their needs by assuming those reported in the situation (B), described below, and to the latter must, therefore, be referred automatically.

If such people develop more severe symptoms, they should be referred to the hospital for investigations and appropriate treatment and leave the telemedicine assistance programs.

## **B. Persons not affected by pathologies before the time when isolation was needed, who exhibit mild to moderate symptoms compatible with COVID-19 infection and who fall under one of the definitions of suspected, probable, or confirmed cases (C.M. 0007922 – 09/03/2020).**

In this situation, we find the people of types 2 and 3 of the ISS Working Group on Prevention and Control of Infections already mentioned (12). In addition to the actions that contrast the spread of the infection, for these people the medical monitoring of the evolution of clinical situations is necessary to provide the best home care and immediately grasp the signs and symptoms of any aggravation, such as to indicate the hospitalization.

For these people the main needs that can be met at a distance are:

- B(1) daily verification of the evolution of symptoms, also using digital medical devices to transfer data directly to the reference health care, if necessary;
- B(2) carrying out medical checks utilizing videocalls;
  - the same requirements A (2), A (3), A (4) listed above for situation A.

### **C. People suffering from chronic diseases, rare diseases and people in conditions of fragility, or who require long-term treatments or special non-hospital care and / or support, and who need to maintain the continuity of services during quarantine, isolation or during the period of application of the social distancing rules.**

All people of type 5 are in this situation, but they can at the same time fall into one of the other four types of the aforementioned ISS Working Group on Infection Prevention and Control (12). For these people, the medical and assistance needs that can be met at a distance and related to their basic pathology appear with a not inferior meaning to the needs concerning the contrast to infection or those for keeping under medical control the symptoms of COVID-19.

Precisely in these people, the appearance of even mild or moderate symptoms of COVID-19 must determine a very rapid and targeted health response, trying to prevent the possible overall aggravation of the clinical picture or limit any difficulties that negatively insist on the individual situation. In this sense, during the entire period of the health emergency for COVID-19, it is prudent to provide telemedicine services, as far as objectively possible, to all people who fall into this third situation, regardless of whichever definition of “case” or “close contact” can be associated.

For these people the main needs that can be met at a distance are:

- C(1) daily verification of the appearance and possible evolution of the symptoms related to COVID-19, conceptually superimposable to people in situation b), but with the required level of personalization of care and assistance, according to the cases;
- C(2) personalized surveillance of the basic clinical conditions, for as long as necessary;
- C(3) the provision of specialist controls through video calls, possibly also carrying out those already programmed before the start of the isolation period;
  - the same requirements A (2), A (3), A (4) listed above for situation A.

It should be specified, about the personalized surveillance of the clinical picture in these people, that the choice of signs and symptoms to be kept under control can be organized in pre-established digitalized cards, suitably according to the pathologies taken care of and making sure to leave always to the doctor the possibility to modify them. These operational aspects will be addressed in further specific in-depth documents, considering that even during an emergency from COVID-19, the realization of a telemedicine service includes the assumption of responsibility for defining when it can be indicated in the individual case and which are the methods of alternative service delivery when contraindicated.

The following table summarizes the relationship between the three situations identified and the related needs that can be met at home in telemedicine, with services whose complexity is appropriate compared to the need to implement them quickly. However, it is clear that the aforementioned complexity progressively increases from situation A to situation C, passing from a rigid and standardized operating model to a very flexible one with few or no possibilities to be standardized.

	<b>Situation A</b>	<b>Situation B</b>	<b>Situation C</b>
Care needs that can be met at the home	A(1)	B(1) B(2)	C(1) C(2) C(3)
	A(2) A(3) A(4)	A(2) A(3) A(4)	A(2) A(3) A(4)
Operative mode	full standardized fixed	very standardized low flexibility	poorly/not standardized high flexibility

## The overall purpose for home care services during the COVID-19 emergency

Clinical reasoning on the needs of patients has always guided the operational choices in the individual's care activities, even during emergency/urgency situations, as well as during epidemics. There is no scientific evidence to suggest that the above principle should not apply even during a pandemic.

This general principle also applies to the definition of the objective set in creating a telemedicine service. The technology, however innovative, is used correctly when it allows progress in medical care.

In a general sense, for the current emergency, it can be said that:

**the goal** of a home care service in telemedicine is **to bring medical services to people who are isolated** or who are isolated in fact because of the rules of social distancing, to proactively monitor their health conditions, in relation both to the prevention and treatment of COVID-19 and to the continuity of care that may be necessary for other pathologies and/or conditions that require it.

This general objective is useful for directing organizational actions in the context of a scientifically valid methodology that facilitates their implementation. However, it alone is not sufficient to provide services that are appropriate to individual care at the individual level.

In building these telemedicine services it is also necessary for the doctor to identify which diagnostic, therapeutic and assistance activities can be carried out remotely, with the technologies available and usable by the person concerned. The doctor responsible for the treatment must be able to choose from time to time the combination between organization and technology that proves to be the best, in terms of efficacy and safety, for the person to be assisted. Equipping the patient with technology, however advanced, does not automatically lead him to recovery. The patient can heal if the technology is properly used within clinical reasoning that has as its purpose the care of the individual and not the use of technology.

# Reference principles for implementing home telemedicine services during the COVID-19 emergency

The reference principles found in this section are those considered essential for the realization of home telemedicine services which aim to meet the needs of assistance in the three situations (A, B, C) defined in the previous section. These services have been elaborated about the period of health emergency by COVID-19 and from the perspective of medical care, taking into account the main practical and organizational problems also related to the specific type of services. Some of those that will be mentioned, although not strictly essential, take on a priority nature given the emergency circumstances for which this work was written.

The text also schematically mentions some particularly important technical aspects that healthcare professionals may need to take into consideration in cases where it is necessary to choose between different options in diagnostic and therapeutic procedures (for example the choice to continue home care or hospitalize the patient following a worsening of symptoms not typical of COVID-19). Further details regarding the correct use of digital and telecommunication technologies are the responsibility of sector technical experts and therefore for further details, refer to the documents they produce. However, for those interested, useful indications can be found in the reference standards both regarding the technical certifications on medical devices, and the processing of personal data.

The principles of reference on which the health professionals should linger are the following:

- Preliminary conditions for making telemedicine services possible
- Healthcare responsibility during telemedicine activities
- Diagram of the elements necessary to carry out home services
- Operation of the health video call
- Initial steps for activating the service.

## Preliminary conditions for making telemedicine services possible

We identify below those conditions whose verification is necessary before starting the program for the realization of a telemedicine service during the COVID-19 pandemic. In the short time allowed by the health emergency, the evaluation of the preliminary conditions replaces the analysis phases and the preparatory study for the design of the telemedicine service. This evaluation must be simple and quick to perform and has a meaning for the fact that the emergency telemedicine service must be activated in a short time, which prevents all the analyses and evaluations of a project carried out in non-emergency conditions, which instead usually take months to complete.

The evaluation of the preliminary conditions takes place on two levels:

- individual, relating to each recipient;
- territorial, or considering the situation of the reference territory.

Furthermore, the same evaluation takes into consideration the technological, health, and regulatory aspects, with the detection of territorial information and then also through simple questions during the first contact with the recipient of the service.

There are various practical ways in which to cross the above information in the evaluation of the preliminary conditions. The choice of the method to be adopted in the practical case is essentially based on the characteristics of the territory, without ever forgetting that it is an emergency procedure.

At present, to decide whether it is possible to carry out a telemedicine service in the course of the COVID-19 emergency, it is advisable to collect information on the following conditions as a priority.

## **Conditions referring to telecommunication infrastructures**

### **▪ Connectivity to the home**

It should be borne in mind that the recipient's concrete connection possibilities constitute the real technological limit for any service that uses telecommunication technologies. Inadequate connectivity can be caused by various infrastructural factors (from the conductor used to bring the electrical signal to the home, to the construction techniques of the environments from which you connect, or perhaps simply from the distance from the WiFi router or the nearest mobile telephone antenna), or the type of device being used, but it can also be adversely affected by the type of service made available by the telecommunication operator. For example, it is common to observe in domestic users a marked difference between the download transmission speed compared to the upload speed. This means that a lot of data arrives at the person at home but manages to send little data in the same unit of time. In this situation, the images from the patient at home may be of unsatisfactory quality for use.

In emergency circumstances, to organize the best service for each person taking into account connectivity, it is sufficient to know:

- if there is WiFi or cable connection at home,
- how far from the router the person usually connects,
- what type of digital devices are available and can be connected to the network (smartphone, tablet, laptop, desktop),
- what is the level of mobile connection within the inhabited area,
- which digital medical devices are available at home and if they have Bluetooth LE system,
- if the person collaborates, it is not difficult to guide them to also perform data connection speed tests, both concerning the home WiFi and the mobile network that reaches the inhabited area.

### **▪ Connectivity of the station from where the health personnel operate**

Inside the healthcare facilities, the connectivity of the operating stations is usually ensured optimally. However, it is recommended to perform connection speed tests and verify the real possibilities of the local network to support data traffic for the average volume of simultaneous requests in download and upload, which will be useful both as guarantees of proper functioning at the time of realization and to document its quality in future analyses of the work done during the emergency period. This will not be an additional effort since the applications to perform these tests are very common and easy to use.

A specific case concerns the position of the doctor who works in telemedicine from the place where he is domiciled for the quarantine. In this case, beyond the assessments of opportunity, it is recommended to evaluate the same procedures described above in the paragraph relating to the recipient of the service, claiming from the doctor the execution of the above connection speed tests.

## Conditions referring to the health organization

- **Accessibility of the service**

The remote telemedicine service for people in isolation or quarantine should preferably be active 24 hours a day, whatever their psycho-physical conditions maybe, while there is no evidence that this is relevant for people who are at home only under the rules of social distancing and which do not fall under any of the definitions of a case or close contact (CM 0007922 of 09/03/2020 - annex 1).

Besides, experience shows that the certainty of having the necessary service continuously available usually leads people to use it more rationally and less emotionally.

It follows that, if the remote service is well structured from the start, with differentiated activities offered wisely within 24 hours, it is possible to calibrate and organize the workload in a sustainable way without the need for a huge number of operators. If it is not possible to offer the service remotely in H24 mode, or if it is not considered appropriate, then it will become relevant to make clear to the person, from the first contact, in addition to the rules of access and use by telematic means, the clear and exhaustive explanation of the alternative procedure to be followed at times not covered by the service itself.

- **Medical prescriptions**

The possibility of fully digital prescription during the service provided in telemedicine should always be possible and uniform throughout the national territory for all clinical situations. Furthermore, for the proper functioning of the service as well relevant for the containment of the contagion, it is useful the prescription arrives directly in digital mode at the Pharmacy chosen by the same patient, or to the supply system provided by the Authorities in the areas where this is necessary, and that the whole system is completed where possible with the delivery of the prescription drug at home. It should be noted that the lack of this possibility has greater negative consequences precisely on those people for whom the benefit of telemedicine is greatest, reducing the overall positive effect of the same.

In this regard, it should be noted that from a technological point of view, there are solutions for selecting, booking, purchasing online with home delivery of the objects, which have already been very tested and commonly used by people. Besides, the rules have already allowed the online purchase of non-prescription drugs for some time now, which are also delivered to one's home (see art.112-quater of Legislative Decree 24 April 2006, no. 219 - Online sales by pharmacies and commercial establishments as per DL 4 July 2006, n.223, converted, with modifications, by the read 4 August 2006, n.248; Circular Ministry of Health protocol n. DGDMF 3799-P-26/10 / 2016 having as its object "Online sale of medicines without prescription according to art. 112-quater of Legislative Decree 24 April 2006, n. 219"). The problem on this point, therefore, appears more regulatory than anything else. The most recent Civil Protection Ordinance (OCDPC n. 651 of 19 March 2020. Further urgent civil protection interventions concerning the emergency relating to the health risk connected to the onset of diseases deriving from transmissible viral agents, being published in the Official Journal) takes a first significant step forward in facilitating the complete dematerialization of the prescription in an emergency. Based on this ordinance, it is possible to try in the various territories to organize also this part of the service, but it is necessary to undertake decisively quick solutions, simple to apply in the operational reality, trying not to exclude people who have more difficulty accessing web services. At least the following information must be taken and evaluated first: the number of active pharmacies in the area, their ability to connect the network, their possibility of home delivery of medicines and devices.

## Conditions relating to the security of personal data and digital devices present at the user's home

The management of cybersecurity and data processing issues cannot be entrusted to improvisation or worse abandoned without unacceptably increasing the risk of intrusions, criminal activities, and undue use of patients' health data.

Healthcare professionals acting in telemedicine are required to observe the rules relating to the correct processing of patients' data, as well as to avoid behaviours that can facilitate possible attacks.

In this regard, in clarifying that the behaviours required of healthcare professionals to protect patients' data are simple and do not require specific technical knowledge, please note that an information document is published on the ISS website dedicated to healthcare professionals<sup>1</sup>.

### ▪ **Cybersecurity management**

Concerning cybersecurity, it is correct to insist that the medical systems for telecontrol offer guarantees of the best possible IT security, regarding the performance of the activities of the health personnel. The use of extemporaneous solutions with uncontrollable social platforms is to be reserved for situations of extreme ratio when it is impossible in an emergency to resort to other solutions for managing contact with patients.

On the other hand, high standards of cybersecurity cannot be expected on the patient side, since, certainly in this emergency phase, to make remote services possible, the telemedicine system must necessarily put pressure on the use of the devices present at the domicile of people, addressing the risks related to it as best as possible.

On this point, it is necessary to ask the health organization for the widest possible guarantees to cybersecurity concerning the digital systems used, and request health workers to adopt protective behavior during remote work. Even more important is to adequately inform people at home without unnecessary bureaucratization of procedures so that they are aware of the data security risks on the system used and at the same time of the advantages that the remote service offers them.

### ▪ **Adherence of the system to the GDPR**

The systems commercially available and dedicated to health care are practically always adherent to the GDPR, to which they necessarily had to adapt before the health emergency. There are no solid reasons to suspend the application of rules already well implemented in the technological and organizational field. If particular situations should arise, deriving from the state of the health emergency, for which the application of the rules on data processing should prejudice the supply of services, then it would be desirable to share a specific solution with the Guarantor for the processing of personal data. It should also be considered that the desist from applying the rules, even in the event of an emergency, does not find justification given the presence on the market of dedicated systems adhering to the GDPR.

### ▪ **Impact on services of DM software certifications**

The issue of rules relating to the certification of medical devices is complex and the responsibility of the sector technicians. The main reference standard is the EC Directive 93/42, in which the software that provides the doctor with elements useful for making decisions for the patient are considered to all effects of medical devices and, therefore, they must have the required certification to be used.

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<sup>1</sup> Good practices for IT security in health services, Guidance document of the National Study Group on Cybersecurity in health services - downloadable from:  
<https://www.iss.it/documents/20126/0/Buone+pratiche+per+la+sicurezza+informatica+nei+servizi+sanitari+17+06+2019.pdf/e4e4a032-a489-b8df-f25c-602ebbb38e85?t=1582512681887>

The aforementioned certification provides for different classes which correspond to increasingly stringent quality and safety requirements and consistent with the intended use.

As said from the beginning, this work is aimed at health professionals who find themselves operating in telemedicine or who actively participate in the realization of telemedicine services in the present emergency health situation. Therefore, in this document, we will not even go into this so specialized technical topic, except to remind the health professionals that during the execution of remote medical-assistance procedures the possible use of the software is, however, their responsibility, even if it is not properly certified or worse from unknown and unverifiable provenance (as could happen for apps downloaded in an imprudent way).

Further technical insights on the topics of this paragraph are outside the scope of this work and therefore refer to specific documentation.

### **Conditions referring to the possibility of a person at home to collaborate**

- **Autonomy in the use of digital systems (of the recipient)**

In addition to complex technological systems, telemedicine services also require the human ability to interact with these systems. For a telemedicine service to properly work, the patient must be trained in its use. Over the years the practical importance of this concept has been better understood and nowadays in the phases of access to the service the patient is progressively instructed on his complete and correct use of the proposed telemedicine system, with various forms of tutorials. During this initial period, the staff also checks to what extent the person can interact with the necessary technologies. A person who needs a telemedicine service cannot always really use it. In this case, the patient normally referred to other solutions with physical presence also this should occur in the circumstances of the health emergency, as mentioned before.

In the specific case of telemedicine services that can be started in an emergency COVID-19, it is more likely that there is no time and resources to support the patient and gradually facilitate the correct use of the service. This especially occurs when the patient needs to frequently and manually send clinical data to healthcare professionals to allow remote monitoring. Some people also have difficulty managing connections, both to the outside and to any devices at home.

Because of these problems, the graphic interfaces should be as simple and intuitive as possible, that the instructions are simple to follow and available both in writing and in voice and that the staff in charge make the first contact with the recipient of the service, or with his caregiver, utilizing a phone call. In this first contact it will be possible to explain to the person the type of service offered and indicate the most appropriate way to connect via video call for further and more detailed explanations and instructions. Numerous technological solutions are available for video calling, very intuitive to use, even from smartphones and tablets. During the dialogue in the first video call, information may also be requested to assess to what extent the person can collaborate with the system made available, particularly for sending the data to the referring doctor.

Despite appropriate explanations, the patient who is unable to connect via video call will be unlikely to be able to use a telemedicine service in the current emergency conditions, since he would find himself using a series of digital devices to send data to the doctor and perform regular remote controls, without having had the time and the way to get used to it. The regularity of controls, which presupposes that of data collection and that of connections, is an indispensable factor for offering adequate guarantees of health security. This gains importance the more difficult it is to physically reach the patient in case of need and the shorter the time available to consider an eventual intervention in the presence effective. The first factor depends on the environmental conditions, the second depends on the organizational ones, and on the type of pathology that you want to keep

under control from a distance. The above aspects must be carefully evaluated by health service managers.

- **Connectivity costs**

Although many operators currently offer routinely contracts in which internet traffic is unlimited or controlled on much larger volumes than what a person in common use normally needs, it is advisable to notify the person for whom the service is intended that traffic data with the activation of home telemedicine will necessarily be higher than usual. In the event of an emergency, solutions are however desirable that avoid *a priori* higher costs for the recipients of the services.

## Health responsibility during telemedicine activities

In general terms, for health professionals, acting in telemedicine means assuming full professional responsibility, even for the smallest action taken at a distance. Specifically, the correct management of the limitations due to physical distance is part of the aforementioned responsibility to guarantee the safety and efficacy of medical and care procedures, as well as compliance with the rules on data processing. The limitations that cannot be filled with technologies or organizational arrangements, if anything, lead to different degrees of involvement in operations. Moreover, these degrees of involvement are to a large extent also foreseeable on the characteristics and the endowment of the specific care setting. These principles apply in any operating situation, therefore also in the present emergency from COVID-19.

In this context, also to manage clinical risk and health responsibility, the correct professional attitude consists of choosing the operating solutions that offer the best guarantees of proportionality, appropriateness, efficacy, safety, and respect of human rights. In summary, it is not a question of choosing the technologies, but the doctor must choose the combination of them that appears the most appropriate from the medical-care point of view in the individual case (20) (21).

It is recommended to apply these concepts in the practical applications of telemedicine also in the present emergency, where, as mentioned above, it is of particular importance to be able to control patients at home using, but not exclusively, the video call tool.

In this regard, reference is made to what has been said about the limitations in uploading to the patient's home and those consequent to the infrastructural characteristics, which can also significantly lower the quality of the image from the patient whatever the software application that generates the images video.

Besides, it should be borne in mind that the use of class 2a medical devices for the correct management of images during television has been recommended for some time since the real-time transfer of video and audio images is essential for effective clinical and organizational efficiency. Such devices cannot be expected to be found in the patient's home. Therefore, the execution of a television set, using the term in the current scientifically validated meaning of medical examination carried out in telemedicine (22), is insecure when using digital tools present at the patient's home to carry out the video call.

It should be noted that it was established all medical and ethical rules of the health professions are exactly applied to telemedicine health activities, as well as the bioethics guidelines. At the same time, in the current emergency, it is necessary to facilitate remote monitoring of patients by reference physicians, including specialists, in every possible way. Therefore, even in not perfect practical conditions, it seems acceptable that the videocall can be used by the doctor to support the clinical control of those patients that he already knows for having previously visited them at least once. It will not be possible to perform real medical tele-examination, but specialists will be able to carry out medical tele-control (data and videocall) on already known patients with reasonable clinical safety.

These activities, when provided with correct procedures, can certainly be recorded and reported.

## Diagram of the elements necessary to carry out home services

The elements necessary for the realization of home-based services in telemedicine are listed concerning the current emergency and according to the reference model illustrated below. This scheme must be understood as the set of minimum and sufficient elements to create a service that is quickly available and equipped with the features that allow you to easily reach the largest number of people at home and provide them with the necessary in an emergency.

### Basic features

- 1a) Connection network always active between doctors and patients with services available in the Cloud (this to ensure that the system can be activated in a few days and on a large scale).
- 1b) Web portal that doctors access with their account to manage all assigned patients.
- 1c) Access to the web page from notebooks or tablets or smartphones for health professionals (through a special App).
- 1d) Ability to create online groups (e.g. by disease, by area) by associating the corresponding doctors and patients.
- 1e) Simple patient login, by downloading an App compatible with all smartphones and they must be able to access the service with their account, with identity verification.
- 1f) Compatibility with the GDPR for the processing of personal data.
- 1g) The isolated person connects to the internet with the digital tools he has available (computer, tablet, smartphone). If the person's computer does not have a video camera and headphones/microphone, they can always be sent home.

### Tools to support the activities of healthcare professionals

- 2a) Synoptic framework to follow the status of all patients assigned at all time
- 2b) Access to history (measurements and trend graphs) or the patient's medical data (PHR).
- 2c) Management of medical history, measurements (synchronous and non-synchronous), doses, appointments, notifications.
- 2d) Interface suitable for managing the objectives, the lower and upper threshold values, and the corresponding alarms.
- 2e) Differentiated systems for communicating with the patient (SMS, an email with encrypted texts, video communication).
- 2f) Video call to the patient with easy-to-use systems for the patient directly from the App, preferably with web-based systems, in which it is not necessary to install any software on the device in use.
- 2g) **Health Coordination Centre\*** that manages the telemedicine service activities. The organization of the aforementioned Centre can be of various types, but with additional support staff to the health professionals who manage patients in telemedicine and with dimensions proportionate to the

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\* **Health Coordination Centre**

It is a physical or virtual centre which performs the connection and operational coordination of the medical-care activities provided in telemedicine and the interaction with other operational functions. This concept of the Health Coordination Centre differs from that of the Service Centre, already present in the old National Guidelines for Telemedicine (2014). In the current state of knowledge, these two centres are both needed in the practice of telemedicine services.

overall workload. The Health Coordination Centre must be managed with continuous monitoring to assist incoming videocalls from users and route them.

Please note that technical support functions, including help desks, are performed by the Service Centre.

### **Support tools for the patient**

- 3a) Performing measurements with digital medical devices equipped with Bluetooth LE connectivity, which are preferably also equipped with a display of the measurement to make human communication of the data always possible as a precaution in case of need.
- 3b) The devices that can be useful are different on a case-by-case basis and the choice of which ones to use pertains to the doctor who has the responsibility of the patient in telemedicine, given the real availability of the objects (see later, section "Types of telemedicine services home"). In the specific case of checking the symptomatic picture from COVID-19, for home telemedicine services, it is recommended to consider the following minimum set of devices: thermometer, scale, pulse oximeter, sphygmomanometer. Other devices can then be added as appropriate (for example it may be preferable to have an ECG at the home of an already heart patient and suspected case COVID-19).
- 3c) App that allows both the automatic connection between devices with Bluetooth LE or smartphone and manual insertion of measurements if necessary.
- 3d) App that allows receiving notifications and/or alerts for medicines, videocall appointments, or for other activities.
- 3e) App that allows access to your measurement history.
- 3f) App that allows you to receive/request a video call to the doctor (see the previous paragraph).

### **Health videocall operation**

The Apps and the portal on which the staff in charge operate must be configured to activate and manage the videocall. The patient must be able to request an appointment for the videocall.

It is useful that this can be done in two ways, both of which must be available:

- 1) the doctor can call the patient via video call if this is online. The patient accesses the call but cannot call the doctor. The doctor can invite at least three users at the same time (medical videocall with simultaneous teleconsultation);
- 2) the Health Coordination Centre (see the previous section) must have access to the web video-center functions, and consult lists of all online users and all medical / psychologists.

It is always advisable to remind the recipient of the service that the operator of a reference with whom he carries out the video call may not always be available, but that there will always be another operator who will answer, sharing the information with colleagues.

In the event of a health emergency, the two methods indicated above to activate the videocall should be available without additional implementation activities in order not to lengthen the activation times, let alone add additional development costs.

### **Initial steps to activate the service**

The following activities are to be considered a reference sequence (not the only one possible) for the activation of the home service in telemedicine, in the simplest way possible for the patient:

- a. The isolated person is reached on the phone by authorized personnel who explain to him/her the offered service and what to do for the connection.
- b. The isolated person connects by downloading a special self-configuring instruction App and proceeds with the activation of the service following the procedure indicated.
- c. At the end of the connection and activation procedure, an initial videocall is started with the first contact point that provides feedback that the procedure has been successful, identifies the person, and communicates to the person the date and time of the first interview with the doctor made available for the emergency.

The identification of a person must be carried out preliminarily for any health act and therefore also in the videocall. The methods for identifying people remotely are of various types. In the absence of other suitable tools, given the emergency, a concrete possibility consists of starting the videocall asking the connected person to show himself and at the same time show his valid ID with a photo on the video camera, noting the details of the document itself.

- d. At the first interview with the doctor, the person's care needs are assessed, according to the three-type situation scheme (A, B, C, see the specific section above). Based on this assessment, the person is assigned to the relative care path. Both interviews and controls are scheduled with the necessary intervals during the period of isolation and according to the cases as well to the available resources (see the following section on the types of services).
- e. From that moment on, the person can still request the videocall service from the referring doctor when he/she wants.

The technological issues to guarantee access security will be defined by the technicians appointed by the health organizations in the individual territories.

# Types of home telemedicine services

This document proposes the structuring of four different types of telemedicine services to best meet healthcare needs (situations A, B, C).

Each of these services can be created and delivered individually. With appropriate technical precautions, the four services can be associated with each other in various combinations, or still created all within a single telemedicine system.

For simplicity of presentation, in this document the realization option in which all four types of services are present will be considered.

The four services can be applied on a single territory, but they can be extended in a modular form to further areas, even if not contiguous to the first, or be replicated in a separate form, but in the latter case, it is necessary to duplicate all the parts that compose it, including the relative health coordination centres (see section "Diagram of the elements necessary to carry out home services").

It is useful to underline, before going into the details of the different service types, that they are not addressed to a specific category of doctors but they can work with the collaboration of any doctor. This is consistent with the emergency health situation and in particular should the relative shortage of doctors increase. However, the organization of remote work provided in these services is appropriate especially for collaboration with GPs / PLS, who can contribute better than others to the more precise assessment of the situation and evolution. For their knowledge of the patients, they can insert in the system the baggage of their specific knowledge of the patients entrusted to them, with anamnestic details, considerations, and for the same reasons they can make a fundamental contribution to the management of the therapy, especially for the chronic patients.

The four TYPES of telemedicine services are illustrated in the following paragraphs.

## **Type 1. Active tele-control of the health status of people in the situation (A), to detect the possible appearance of signs and symptoms of COVID-19 infection**

This type of service is aimed at people related to the situation (A), already illustrated (*"people not affected by pathologies before the time when quarantine or isolation was necessary, asymptomatic and who fall within the definition of close contact or confirmed case (CM 0007922 - 09/03/2020 )"*).

The type of service is proposed to immediately identify in such people the appearance of symptoms and/or signs attributable to the beginning of the symptomatic phase of COVID-19.

This service finds its direct utility in the remote control of the spread of the contagion, with a clear utility in the overall management of the emergency by the Authorities, but it also has an individual utility as it allows to make the treatment of support to the individual, increasing their chances of recovery. Furthermore, it facilitates the correct adoption of home hygiene and prevention measures by the person himself and any cohabiting partners.

Healthcare personnel must operate in a coordinated manner concerning the Public Health Services of the relevant territory, to optimize the use of resources and must also act according to national provisions and guidelines, to ensure uniformity of procedures and performance.

The remote control activities can be performed by adequately trained healthcare personnel, are based on repetitive and standardized procedures for anamnestic updating and detection of some simple objective signs (e.g. body temperature), together with scheduled interviews in a video call in which they occur the

data collected and information on the state of health. At the same time, during the video call, the person is provided with useful information and advice. These regularly scheduled contacts also help to improve individual adherence to indications, prescriptions, and treatments.

For this type 1 of service, the objective data that must be collected are all that is indicated by official sources as necessary and sufficient to make the clinical diagnosis of COVID-19 or at least to suspect it (23, 24).

The clinical symptoms that were most commonly found in COVID-19 cases later confirmed in the laboratory were the following (25, 26):

- |  |   |   |
|--|---|---|
| <input type="checkbox"/> fever (88%)             | <input type="checkbox"/> dyspnoea (19%)             | <input type="checkbox"/> diarrhoea (4%) |
| <input type="checkbox"/> dry cough (68%)         | <input type="checkbox"/> sore throat (14%)          | <input type="checkbox"/> vomit (5%)     |
| <input type="checkbox"/> fatigue (38%)           | <input type="checkbox"/> headache (14%)             | <input type="checkbox"/> dysgeusia      |
| <input type="checkbox"/> sputum production (33%) | <input type="checkbox"/> myalgia o arthralgia (15%) | <input type="checkbox"/> anosmia        |

Reports in China report that symptoms were mild to moderate in 80% of cases, including those who had pneumonia (27-29).

It is advisable to include all these symptoms in the computerized procedures for detecting anamnestic information and control, asking the person in isolation to indicate only if one or more of them are present. This can also be done through the questionnaire in the App or during the video call interviews and is used exclusively to identify people in quarantine or isolation who become symptomatic or paucisymptomatic.

However, in practice, the first symptoms to keep under control, to monitor the onset of COVID-19, are dry cough and cooling symptoms, which can initially appear even in the absence of fever, as is the appearance of fever among 37.5 and 38.5°C the objective sign necessary and sufficient in the situation (A) to admit the probable transition to a paucisymptomatic form, being reported in all works as a far more frequent sign (30-32). The detection of body temperature recommended twice a day as per usual medical practice, can be carried out with any thermometer and various technological solutions allow you to send the data directly in digital format to the reference platform.

In this type of service, the video call, preferably with the GP / PLS, must be timed, but with rhythms decided by the doctor himself, who assesses to what extent this is appropriate for the patient he knows.

Once intercepted with the remote control the moment in which a paucisymptomatic picture occurs (fever between 37.5 and 38.5 ° C, dry tickling cough, symptoms of cooling and/or other symptoms indicative of COVID-19, see above) and without dyspnoea, the person concerned must be automatically referred to the type 2 service, which allows specific surveillance of the symptomatic trend and treatment. The purpose of this exchange manoeuvre between two types of telemedicine services, with different procedures, clearly consists of helping to give the patient the best chance of recovery in case of aggravation (see type 2 below in this section).

The videocall system for the activities described above, under their nature and always in consideration of the health emergency, does not require the high characteristics that are normally needed to guarantee health security when deciding on differential diagnosis (e.g. precision image) and for which high or maximum level certifications are required. This allows us to be flexible in using various videocall systems to adapt to the technological possibilities available at the person's home.

## Type 2. Tele-surveillance of the clinical picture of people in the situation (B), for the necessary treatments against COVID-19 and to arrange for any hospitalization when appropriate

This type of service is aimed at people related to the situation (B), already illustrated (*“people not affected by pathologies before the time when isolation was needed, who show mild to moderate symptoms compatible with COVID-19 infection and that fall under one of the definitions of suspected, probable or confirmed cases, CM 0007922 - 09/03/2020 ”*).

These are numerous patients who develop symptomatic forms of COVID-19, or symptomatic pictures compatible with COVID-19 in suspicious cases, with mild or moderate symptoms and signs, whose condition is manageable at home and in the absence of further pathologies.

The typical clinical picture of a reference for insertion in this service consists of: fever between 37.5 and 38.6°C, dry tickly cough, symptoms of cooling (and/or other symptoms indicative of COVID-19, see above) and without dyspnoea.

The objective of this type 2 service is to treat the aforementioned patients remotely with suitable treatments, maintaining medical supervision at home, with greater proactivity than would be possible without telemedicine systems, providing an effective and easy-to-use tool for optimize primary care in the current emergency and to safeguard the safety of healthcare.

The insertion of the patient in this type 2 of service is associated with the reporting of the case to the Public Health Services for the execution of the test for COVID-19, where applicable.

The patient can be inserted directly into the type 2 service, or be referred to it from type 1, in the manner described above.

The exchange maneuver from type 1 to type 2 service allows the doctor to be placed in the best condition to recognize as quickly as possible, the moment when the symptoms tend to increase in number and intensity, increasing control in telemedicine.

Severe forms of disease, with more intense symptoms, occur in 13.8% of cases, and 6.1% of patients instead have a critical form of COVID-19 with respiratory failure, septic shock and/or multi-organ dysfunction/failure, with further related symptoms (33-36).

Using telemedicine systems in this mode means treating people at home instead of hospitalizing them, when this is possible and useful for the person, while it does not mean using telemedicine to delay hospitalization that is deemed necessary.

The **symptoms to be monitored** in telemedicine in this service are all those related to COVID-19 (37):

- |   |   |
|---|---|
| <input type="checkbox"/> Fever                            | <input type="checkbox"/> Sputum production    |
| <input type="checkbox"/> Dry cough                        | <input type="checkbox"/> Headache             |
| <input type="checkbox"/> General malaise                  | <input type="checkbox"/> Myalgia o arthralgia |
| <input type="checkbox"/> Anorexia                         | <input type="checkbox"/> Diarrhoea            |
| <input type="checkbox"/> Dyspnoea                         | <input type="checkbox"/> Vomit                |
| <input type="checkbox"/> Fatigue (in standing or walking) | <input type="checkbox"/> Dysgeusia            |
| <input type="checkbox"/> Sore throat                      | <input type="checkbox"/> Dysosmia/anosmia     |

The objective signs whose measurement is necessary for this medical check-in telemedicine and the apparatuses for their detection are listed as follows:

Objective sign to measure	Measuring instrument	Recommended measurement frequency
Body temperature	Thermometer	2 times a day
Respiratory rate per min.	Wearable sensors (Bluetooth LE or other automatic online transmissions) or manual counting	4 times a day
Heart rate	Digital frequency counter (Bluetooth LE or other automatic online transmissions)	4 times a day
Peripheral oxygen saturation (+ heart rate)	Digital pulse oximeter (Bluetooth LE or other automatic online transmissions)	4 times a day; it may be helpful to detect oxygen saturation much more frequently, if necessary
Systolic and diastolic blood pressure	Automatic digital sphygmomanometer (Bluetooth LE or other automatic online transmissions)	According to medical indication
Cardiac electrical activity	Digital ECG (Bluetooth LE or other automatic online transmissions)	According to medical indication

The frequency indicated to measure the aforementioned signs is based on the practice of general medicine and from the major experiences of primary care reported in the international literature (38) (39) (40).

In type 2 service, the appropriate combination of measuring devices can have a high level of standardization, but cannot be rigidly established a priori for all people. The doctor, also based on the interviews with the patient, decides from time to time which measurement scheme is suitable, however choosing from a basic battery of measurements that can partially change and remembering that if necessary the same patient can transmit online the measurements or can report them during the check-up video call with your doctor.

The control videocall, always associated with the detection of the symptoms and signs indicated above, has the meaning of allowing the patient's clinical evaluation and risk conditions at a distance, directly by the connected doctor, to complete the classification of the case to decide the treatment against COVID-19 and above all to react promptly in case of worsening towards serious forms of the disease.

The videocall allows us to partially overcome the limits of simple telephone contact, also transmitting images and colours. In this way, it allows the doctor to perform at least a part of the normal medical examination: entirely the collection of the medical history and partially the physical examination (inspection).

The **clinical evaluation** records the changes of some objective signs of deterioration. This assessment is pertinent to the doctor in the specific case, but taking into account the clinical picture of COVID-19 only, a series of clinical observations can be standardized, possibly to be made in video call even without particular image quality. By way of example, some observations used by doctors of the Continuity of Assistance can be listed (41):

- slowing / acceleration of breathing;
- the feeling of difficult breathing even for light efforts (getting out of bed);
- reduced ability to speak by coordinating breathing;
- fatigue in walking or standing;
- tachycardia at rest;
- peripheral cyanosis (color nail-bed, lips, skin).

The evaluation of the vaccination status (flu and pneumococcal) is useful, too.

The evaluation of the risk conditions, necessary in the first video call and which consists, as in the present, in collecting the anamnestic information useful to frame in the specific case the existence of concomitant pathologies and/or risk factors that can increase the risk of complications:

- lung disease
- heart disease
- kidney disease
- metabolic diseases
- diseases of the immune system
- oncological diseases
- rare diseases
- pregnancy/childbirth
- social unease / frailty
- not self-sufficient

The patient eligible for this type of service 2 should by definition not present any of the risk factors listed above. If one or more of them is present, it must be automatically addressed to the next type 3 of service which will be described below.

Additional health videocalls can always be activated by the responsible doctors, based on the progress of the data automatically detected, or requested by the patient, if necessary, and with established methods to not overload the system with disproportionate requests. In this regard, the correct collaboration of the patients is required and therefore the first contact will be given instructions of behavior to avoid as much as possible irrational requests for unnecessary checks. However, to optimize the service it is appropriate to allow patients as much as possible to request videocalls to report any significant change in the symptomatic picture before the scheduled appointment, as well as to request the psychological support videocall (see type 4 below).

### **Type 3. Active tele-surveillance of the overall clinical picture of people in the situation (C), to provide the best possible continuity of care and assistance at home, concerning the basic condition and any COVID-19 infection.**

This type of service is aimed at people related to the situation (C), already illustrated (*"People suffering from chronic diseases, rare diseases and people in conditions of fragility, or who require long-term treatments or special assistance and / or support not hospitals, and who need to maintain the continuity of services during quarantine, isolation or during the period of application of the rules of social distancing "*).

The objective of this type 3 of service is to continue the care and home care in favor of the aforementioned patients respecting their basic condition while placing them under the maximum protection obtainable against COVID-19. For these people, the damage caused by the interruption of care and assistance following forced isolation or social distancing has equal importance to that deriving from the infection. The development of COVID-19 in people already suffering from other demanding pathologies, with reduced functional reserve, can more easily induce extreme consequences in a short time, but the interruption of the necessary treatments will cause damage that is difficult to recover, which will occur in longer times but equally with serious consequences.

For these people, telemedicine systems must be used to keep the services dedicated to the active, modifying, if necessary, the procedures to obtain the widest possible accessibility and usability at a distance

while maintaining medical control for both primary care that for specialist services and also in these cases, safeguard the safety of health.

The patient can be inserted directly into the type 3 service or be referred to it by type 2 in the manner described above.

The exchange manoeuvre from type 2 to type 3 service allows the doctor to be placed in the best conditions to keep the basic pathological picture under control and at the same time monitor any appearance / evolution of symptoms and signs from COVID-19.

The operating procedures relating to COVID-19 in this type 3 service are identical to those reported in types 1 and 2. However, in the telemedicine activities to combat COVID-19 aimed at these patients, measures of greater protection are applied based on the cases.

The remote-control procedures are performed by the medical personnel identified based on the needs and available resources. They are based on activities for the detection of symptoms and objective data, together with videocalls scheduled daily, in which the clinical situation is updated and the adherence and therapeutic efficacy are verified, in particular about:

- appearance/evolution of the symptoms related to COVID-19, conceptually superimposable on people in situation b), but with the level of personalization of the required care and assistance according to the cases;
- evolution of the basic clinical conditions, for the whole necessary period;
- the provision of specialist checks through videocalls, possibly also carrying out those already programmed before the start of the isolation period;
- surveillance on the correctness of the treatment of the underlying pathology or assistance for the specific condition of the person.

At the same time, the person is provided with information and useful advice for the management of his specific condition.

When symptoms appear, the telemedicine system using the checks of the data detected by the devices and together with the daily verification of the doctor by videocall must allow the doctor to prescribe the appropriate and personalized treatment at home, as well as to immediately identify situations of worsening of conditions requiring greater care in a hospital setting.

Concerning the items in the list above, it should be borne in mind that, even in the emergency of COVID-19, the task of telemedicine services offered at home for these patients essentially consists in limiting the frequency of episodes of exacerbation of the chronic pathologies and/or in preventing complications, reducing as much as possible the need for services in which to go to health facilities is essential. This task can be performed in part or whole by detecting and transmitting the necessary and personalized set of clinical parameters to the referring physician, as already extensively studied and applied in telemedicine. However, in the emergency it is possible to be forced by circumstances to organize home services in telemedicine having to accept the limits of the available hardware and software close to the patient.

In cases where it is not possible to deliver the necessary tools to the patient or he/she or the caregiver is unable to use them acceptably, an appropriate sequence of alternative actions must be organized until the material resources available are such to guarantee safety and efficacy. It is already recommended in the organizational phase to define in which situations the assisted patient must be directed to in-patient services, which in turn may be either at home or in health facilities.

## **Type 4. Psychological tele-support concerning the inconvenience and limitations of isolation (at the request of people)**

This type of service is aimed at any person who is in solitary confinement or quarantine, or isolated in fact as a result of the rules of social distancing, under COVID-19.

The purpose of this service is to put the isolated person in contact with a psychologist in audio-video (42). The videocall is activated on individual requests, with a procedure that allows the service to be directly delivered as quickly as possible, based on the resources available at the person's home.

It is particularly indicated and recommendable also for this type of service 4 that the coordination of the activities is assumed by the competent Authorities. This type of activity cannot be standardized by definition and therefore coordination only serves to optimize the provision of the service to guarantee uniformity, above all for the application of scientifically correct and safe intervention methods. The interviews will however be subject to the code of ethics of the Order of Psychologists and will not be recorded.

The service does not consist of medical-assistance activities but consists exclusively of conducting interviews with a psychologist, which are intended to support people in isolation from the inconvenience, limitations to relationship life, and fears caused by the specific situation.

The psychologist, identified by the professional register, interacts via videocall with the people who request it and can agree on further videocall interviews with the person, once the first contact has been established and where he deems it necessary.

Before starting the interview, it is recommended that the psychologist identify the person to whom he addresses, using the most appropriate methodology possible, possibly also using the method already suggested in point c. in the paragraph "Initial steps for activating the service".

The video call system for psychological interviews, under their nature of individual interviews without the use of the equipment and always in consideration of the health emergency, only requires good connectivity that allows the psychologist adequately to grasp even non-verbal language during his speech.

## Application limits for home telemedicine services

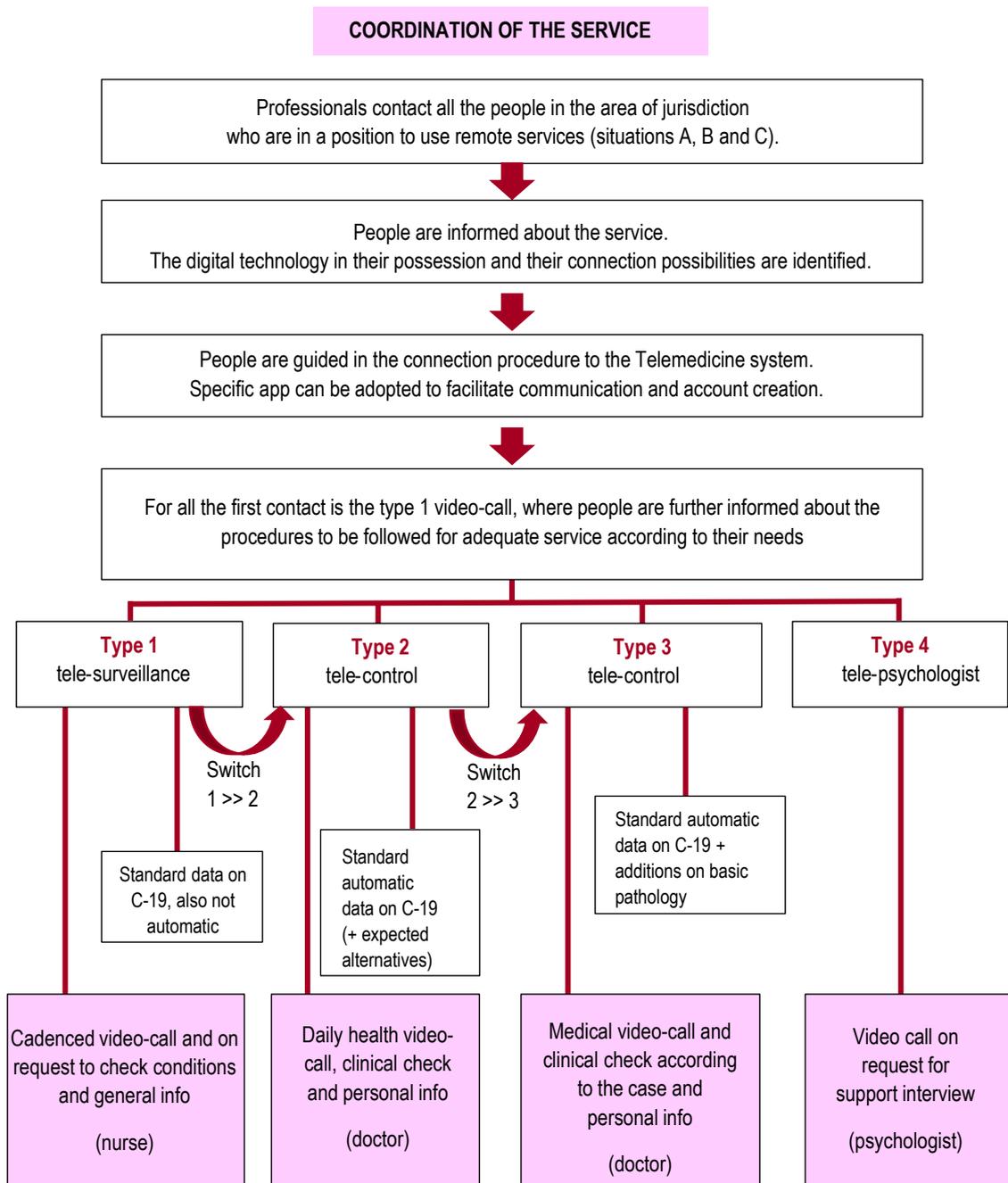
Since there is no significant previous experience of using these systems in emergencies of pandemic health and although the use of telemedicine systems for emergency / individual emergency interventions has long been affirmed with solid scientific evidence, it is not recommended to precautionary measure, the use of telemedicine services offered in this work, in the following situations:

- Patients not known before the health emergency who at the first contact shows even one of the following signs: altered state of consciousness, dyspnoea at rest, systolic pressure less than or equal to 100 mmHg (if this measurement can be performed at the patient). In these cases, it is indicated to immediately send the patient to the hospitalization in urgency, according to the procedures provided.
- Patients with acute pathologies or exacerbations of chronic pathologies in progress, even if addressed to isolation (except for small traumatismos that can be managed, except for complications, in the home setting);
- Patients with chronic diseases and frailties or with disabilities that make it imprudent to stay at home in the presence of COVID-19 symptoms.

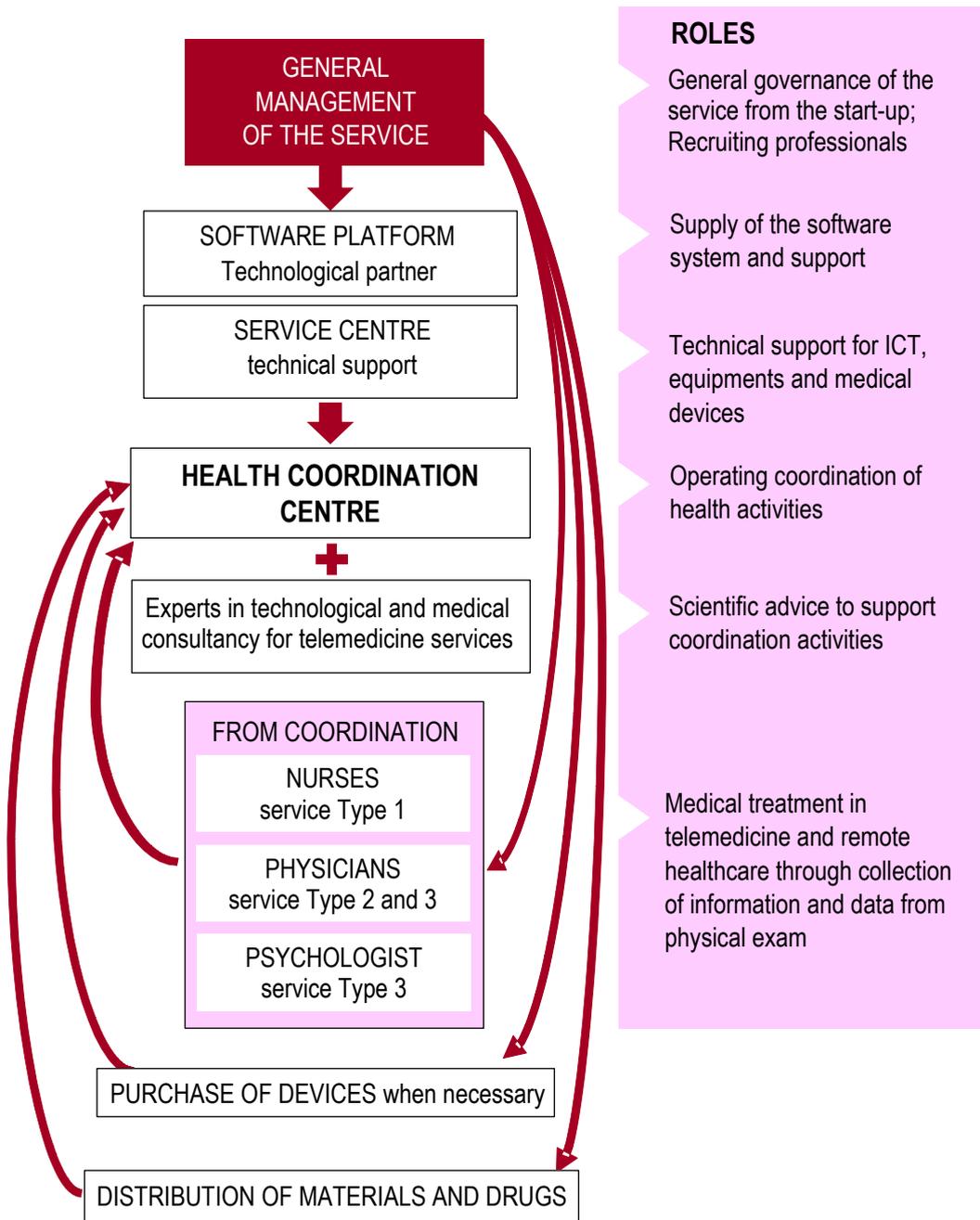
Of course, the final evaluation of the instruments suitable for the individual patient is the responsibility of the doctor.

# Functioning scheme of the proposed telemedicine services

Version with 4 types of services provided remotely by a single system. The system can be used in a modular way even with only one type of service, obviously in this case it is not possible to pass patients from one type of service to the next.



# Organization scheme of the telemedicine system



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