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RESEARCH ARTICLE

Early Home Therapies against Covid-19 An Italian Case of Politicisation of Science?

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ABSTRACT: Since February 2020, strategies aimed at containing and managing the Covid-19 syndemic have been developed by the governments of European countries. Among these measures, the possibility of an early treatment of the disease has been considered of fundamental importance, both for curing the disease and governing the syndemic. Despite their potential, early therapies received a somehow unexpected treatment in Italy and the debate around them gave rise to a very evident conflict between proponents and opponents of those treatments, to the point that some of the former organised a properly political movement in order to promote the integration of early home therapies in the official health protocols. Not surprisingly, the issue of early therapies has been considered an exemplary case of politicisation of science. However, the assimilation of the early therapy controversy to the frame of politicisation of science cannot fully explain why these protocols were discarded by political and health authorities. Rather, the consideration of health protocols as socio-technical objects shifts the attention on the vast range of cultural, political and economic factors that contributed to the general resistance towards those treatments. Therefore, we aim to analyse the media coverage of the phenomenon, and investigate the protocols of home treatment of Covid-19, paying attention to the interaction of the factors that contributed to the exclusion of home therapies into national guidelines.

KEYWORDS: Early Home Therapies, Covid-19, medical protocols, politicisation of Science, scientific conflicts, socio-technical-scientific objects.

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1. Introduction

Since February 2020, strategies aimed at containing and managing the current Covid-19 syndemic[1] have been developed by the governments of the European countries. Among these measures, the attempt to treat people suffering from Covid-19, a disease whose course was then largely unknown, has been particularly important. The first European country to be severely hit by the spread of the virus, Italy, had to face the so-called "first wave" (February-May 2020) in a context of high uncertainty. After a first period of initial bewilderment, when the majority of symptomatic patients were hospitalised, hospitalisation was restricted to severe patients only, i.e. those suffering from an advanced stage of the disease. Covid-19, in fact, varies greatly in the manifestation of symptoms: its clinical spectrum can include asymptomatic and paucisymptomatic forms, as well as more severe forms that can lead to death. In the early months of the spread of the virus, due to quite ambiguous governmental indications and the little information available at the time, several hospital doctors and general practitioners began to offer "early" therapies, i.e. treatments that could prove effective even in the early stages of the disease, so to prevent its worsening.

The possibility of an early treatment of the disease has been considered of fundamental importance, both for curing the disease and governing the syndemic. The provision of "early" or "home" treatment would be beneficial in avoiding the overburdening of emergency rooms and hospital wards, in preventing the multiplication of contagions within these facilities, and finally in guaranteeing better monitoring of patients and control of contagion in the pre-hospital phase – the one that most escapes the control of health authorities (Basta et al. 2020).

In this regard, the case of Italy is particularly interesting: not only the Italian government was the first in Europe to introduce nation-wide restrictive measures to counter the spread of the virus, but those were severe and long-lasting compared to neighbouring nations. Furthermore, the issue of early home therapies gave rise to a very evident conflict between proponents and opponents of those treatments. On the one side, they were discarded as ineffective or dangerous in the public debate, and opposed or ignored by health and political authorities. On the other, some proponents organised a properly political movement in order to promote the integration of early home therapies in the official health protocols.

Our goal is to understand this process by taking into account elements other than the simple inefficacy of the drugs used in those therapies. Rather, we will focus our attention on the vast ensemble of cultural, political and economic factors that contributed to the general resistance towards those treatments. In order to do so, we will follow two main aims: 1) analyse the media coverage of the phenomenon, with particular interest in the actors who developed home therapies and their relations with political and health institutions; 2) investigate the protocols of home treatment of Covid-19 by paying attention to the interaction of the many elements that contributed to the exclusion of home therapies from national guidelines.

[1] This term is the crasis of the words synergy, epidemic, pandemic and endemic, and was introduced in the 1990s by the medical anthropologist Merril Singer (Singer et al., 2017) in relation to the adverse effect produced by the synergistic interaction between two or more diseases. With respect to Covid-19, the term has been used, also by authoritative sources such as *The Lancet* editor Richard Horton, to foreground the constitutive interaction between Covid-19 and other non-communicable diseases (NCDs), such as cardiovascular diseases, cancers, or diabetes – which have accelerated formidably in Western societies in recent decades. As these "conditions are clustering within social groups according to patterns of inequality deeply embedded in our societies [...] The most important consequence of seeing Covid-19 as a syndemic is to underline its social origins" (Horton, 2020, 874).

In the next section, we will briefly discuss the framework within which health controversies are commonly analysed: that of politicisation of science. After highlightening the descriptive and normative limits of this approach, we will introduce another interpretative framework for the debate on early home therapies, based on the idea of considering medical protocols as socio-technical objects. In the third section, we will discuss the method of our research. The fourth section, instead, will be devoted to a conceptual clarification on what are commonly referred to as "early" or "home therapies" and to an overview of the pathophysiology of Covid-19, so to understand the rationales that underlie the administration of early treatments. In the fifth section, we will provide a reconstruction of the evolution of the Italian public debate on home therapies, while in the sixth we will analyse the scientific protocols of early therapies as socio-technical objects, with the aim to identify the main elements that have favoured or disfavoured the integration of such treatments into the Italian national guidelines. Finally, the conclusive section will highlight the central contradiction concerning the debate on early therapies, and some unresolved issues it revealed.

2. Theoretical framework

At first glance, the Italian debate on early home therapies could be considered an exemplary case of politicisation of science. In general, according to Pavolini et al. (2018), some structural characteristics of the Italian health system – poorly resourced, with major New Public Management reforms and low trust in healthcare providers – render the country itself prone to the instrumentalisation of health issues. Not by chance, cases from the Italian context are frequently examined in comparative studies on health controversies, especially due to the prominence of previous campaigns of politicisation of health in the country – among all, those regarding vaccination (see, for instance, Kennedy 2019; Speed and Mannion 2020; Gobo and Sena 2022). In this regard, the health controversy at hand would represent another piece of the puzzle: proponents of early home treatments were accused of disregarding evidence and defending pseudo-scientific positions, while their supporters were believed to embrace therapies for gullibility or ideological reasons. Some political leaders and movements were blamed for instrumentalising the dispute; users and channels favourable to therapies were charged with spreading conspiracy theories and fake news.

Although, as we shall see in Section 5, such a diagnosis was largely accepted in the Italian public debate, we consider it an extremely simplistic account of the issue. In fact, we argue that the implicit or explicit assimilation of the early therapy controversy to the frame of politicisation of science cannot fully explain why these protocols were discarded by political and health authorities. In the next section, the characteristics and the limits of the interpretations that rely on the concept of politicisation of science will be illustrated in order to better understand this outcome, and, in the following section, a different framework to read our empirical case will be advanced.

2.1. The frame of politicisation of science

Both in academic and non-academic debates, the concept of politicisation of science is used to refer to those situations where a social actor makes an instrumental use of a scientific controversy to gain some advantage in terms of visibility, consensus or profit. Based on some previous works on the topic (Jasanoff 1987; Pielke 2007; Oreskes and Conway 2010), Bolsen and Druckman (2015) identified some distinctive features of this strategy: first, "politicization is about emphasizing the inherent uncertainty of science to cast doubt on the existence of scientific consensus" (2015: 747); however, and secondly, it does not always come from a strictly

political actor: "the source of politicization could be an interest group, a fellow citizen, or any other actor" (*ibid.*). Although the authors clarify, as a third element, that politicisation "is not misinformation per se" (*ibid.*), several works adopting the approach of politicisation of science (Speed and Mannion 2017, 2020; Lasco and Curato 2019; Lasco 2020; Lasco and Larson 2020; Żuk and Żuk 2020) recurrently associate the concept with some epistemic, cultural or cognitive deficits:

- distrust towards intellectual authorities, medical institutions and professional expertise;
- replacement of scientific evidence and factual knowledge with ideological theses, folk wisdom and false claims;
- inclination to emotionality, prejudices and conspiracy thinking;
- recourse to dramatic, oversimplified and populist styles;
- reliance on post-truth, fake news and alternative facts.

Despite its apparent clarity, we consider this approach of politicisation of science highly problematic, both in its theoretical assumptions and its heuristic capabilities. On the former level, this framework often resorts to elaborate epistemological categories (evidence, facts, ideology, falsehood, post-truth) and conceptual distinctions (political vs non-political, science vs pseudo-science, experts vs non-experts, reason vs emotion) as they were taken for granted, without any need of discussion or further clarification. As a consequence of these theoretical limitations, we argue that the approach of politicisation presents science as a very narrow and autonomous domain. By doing so, nonetheless, it seems to offer a simplistic picture of health controversies, and appears to be inspired by a strong normative orientation: any deviation from an (alleged) scientific consensus is to be condemned; science is to be kept untouched by politics, economic interests and cultural biases; scientific evidence is to be considered the only source of legitimation of (health) policies.

In opposition to this interpretative model of health controversies, our contribution aims at reading the Italian debate on early home therapies through a different framework. We do not intend to offer an alternative theory of the politicisation of science, nor a brand-new, comprehensive theory of health controversies. Rather, as we will deal with the specific issue of the failed integration of the early home therapies protocol into the Italian guidelines for treating Covid-19, we will limit ourselves to build a context-sensitive conceptual toolbox centred on the interpretation of scientific care protocols as socio-technical objects.

2.2 Scientific care protocols as socio-technical objects

In sum, one can say that the approach of politicisation of science ascribes the problems arising from health controversies to an illegitimate process of appropriation or interference of science by other domains (especially politics). However, as we anticipated, this diagnosis is based on a hard and straightforward delimitation of the sphere of science – a view that Science and Technology Studies (STS) has long questioned (Jasanoff 1987, 2007; Evans 2022). Especially in those contexts where scientific advice is required to influence policies, as in the government of a syndemic, the boundaries between the technical and the political sides of decision making are all but established – rather, they "are routinely crossed as scientific advisers make judgements about acceptable risks, reliable evidence and desirable outcomes" (Evans 2022). All the more, in the sphere of health policies, the linear adoption of scientific evidence by political authorities appears to be a hybrid and complex process. For this reason, we will observe the development and adoption of scientific care protocols as the result of socio-technical processes.

The idea of considering treatment protocols in this guise builds on another decisive consideration developed within the field of STS (Gobo and Marcheselli, *forthcoming*). If Lakoff suggested that "pharmaceuticals do not work by themselves but function as elements of a broader system that both encourages and constrains their circulation" (2008, 755), we aim at expanding the scope of this logic. Even the adoption or rejection of care protocols is not to be considered as solely determined by the biochemical action of pharmaceuticals on a given disease, but also as significantly influenced by the systemic, non-linear and often unpredictable interaction of various processes that take place in different, albeit interrelated, spheres:

1. the medical-scientific research and expertise, comprising the physicians administering treatments, the medical-institutional systems in which they are embedded, their specific medical cultures, the lines of research pursued, the process of evaluating the efficacy of treatments etc.;
2. the institutional regulation on the part of ministries, pharmacovigilance agencies, political and health institutions at national, international, central and territorial levels;
3. the media and the public sphere, central in influencing the coverage, the discussion and the possible distortions of a protocol;
4. the agency of patients, drugs and the virus itself, which deeply impact on the development and implementation of a protocol, albeit in very different ways.

It is also worth pointing out that care protocols, as technical-scientific objects, have an eminently and essentially political nature. On one hand, in fact, the "decisions on how to regulate the circulation of pharmaceuticals are critical to the particular effects that they achieve on individual bodies and minds" (Lakoff, 2008, 755); on the other, their success or failure is deeply rooted in very concrete, politically built, controlled and contested environments.

3. Methods

To study the phenomenon of early home therapies, we conducted an empirical research on two sets of data: articles published by Italian media and 16 discursive interviews with experts. With the double aim of obtaining a map of the coverage of the topic and selecting the potential interviewees, we conducted a preliminary inspection of several national newspapers and news sites[2]. Within those sources, we collected all the documents (statements, interviews, articles, comments) relevant to the topic that were published from February 2020 to February 2022. Moreover, we were systematically engaged in integrating or deepening the information

[2] Source selection was conducted in two steps. First, we identified major Italian newspapers (such as *Corriere della Sera, La Repubblica, Il Sole 24 Ore, La Stampa*) and news sites (i.e. *TGCOM24, Fanpage, ANSA, TPI*) based on their circulation and online traffic, as certified by Agenzia Diffusione Stampa and Audiweb. Second, we included in our sources less famous but equally useful news outlets: websites devoted to fact-checking (i.e. *Facta, Butac*), alternative (*ByoBlu TV*), regional/local (*L'Eco del Sud*) and thematic news outlets (*Quotidiano Sanità*). In this way, we were able to observe not only the most widespread opinions on the topic, but also the fringe ones. In order to identify the relevant articles, we searched for the expressions "terapie domiciliari" [home therapies] and "terapie precoci" [early therapies] – combined with the term "Covid" – on both Google Search and Google News, by filtering the research by site. We also filtered our research by time, and selected the articles week by week, thus obtaining detailed insights on how the discussion on early therapies developed while we moved into the observation period.

presented in the articles with more specific research on webpages of political and health authorities (WHO, Ministry of Health, Italian regions), pharmacovigilance agencies (AIFA, EMA, FDA) or scientific journals. At the end of the collection process, we had gathered 237 articles.

Through this preliminary inquire, we were able to identify about 42 experts (and potential interviewees) among those who expressed favourably about early home therapies. Within this group, we further selected 16 of them according to six variables: geographic area of practice (north/centre/south), professional qualification (general practitioner/health care manager/hospitalist), involvement in scientific research (no/occasionally/full-time), gender (man/woman), orientation toward vaccines (very favourable/favourable/unfavourable/very unfavourable), and affiliation to movements or associations promoting early home therapies. Specifically, we performed a purposive sampling, a form of sampling in which researchers choose members of the population to participate at the inquire. The sampling technique option we implemented was Maximum Variation (or Heterogeneous): it consists in identifying participants who comprise a diverse range of statuses on particular attributes/variables so that all possible statuses are present. This allowed us to gain as much insight from as many angles as possible during the study.

The exploration of both documents and interviews was based on the qualitative content analysis (Schreier 2012; Erlingsson and Brysiewicz 2017) we conducted with the aid of a software for textual analysis (NVivo10). As the documents reported the attitudes and opinions overtly expressed in the debate on early home therapies, a qualitative content analysis enabled us to identify the positions of scientists, experts, general practitioners and hospital doctors on the topic, as well as to grasp the issues they encountered when formulating protocols of home early therapy. Apart from providing an interesting result itself, the analysis of documents helped us in three further aspects:

1. obtaining information about the individuals and the groups who developed protocols of early treatments, the context in which they operated, the reactions of the political and health institutions, and the general reception of the topic in the Italian public sphere;
2. formulating hypotheses about the causes why early home therapies were not integrated into the official protocols for treating Covid-19;
3. constructing the interview outline and guiding us during the interviews themselves.

In order to analyse the text of the interviews, we devised a checklist (see Atkinson 1992; Silverman 1993; Gobo 2008). After a preliminary inspection, a coding process was carried out in order to identify the main factors that concurred to the exclusion of home therapies from national protocols, which have been grouped into four categories: 1) medical-scientific research and expertise, 2) institutional regulation, 3) media and public sphere and 4) agency of patients, virus and drugs.[3] Within those different but interconnected spheres, we then identified the factors that, through their mutual interaction, concurred to hinder the inclusion of early therapies into national protocols. These categories emerged during the coding process of the interviews.

The analysis was driven by an abductive reasoning, i.e., a combination of induction and deduction, designed to generate hypotheses to explain certain observations. According to Pierce (1960), abduction is the only form

[3] Consistency and validation of this categorization, accomplished separately by authors, was achieved by an inter-coder reliability (ICR) procedure, based on double-checking their coding process (MacPhail et al., 2016; Lombard et al. 2022). Through this procedure, some initial disagreements between the coders were resolved.

of reasoning that could increase our knowledge[4], as it allows the hypothesising of new ideas through a creative and non-linear thought.

4. Early home therapies: what the hell are they?

Before analysing the conflicts concerning home therapies, it is appropriate to make an initial terminological and conceptual clarification. Although the expressions "home therapies" and "early therapies" are often used in the public debate as synonyms, they actually refer to different, though closely related, processes: the former expression emphasises the place where therapies are administered, while the latter focuses on the distinctive element of this kind of treatment, i.e. that they are administered from the early stages of the disease. The course of Covid-19, in fact, can be summarised in three phases that are responsible for five clinical stages characterised by different symptomatic manifestations of increasing severity (Fig. 1).

In the early stage of infection, the virus enters the body, infects the cells and begins replication. The first

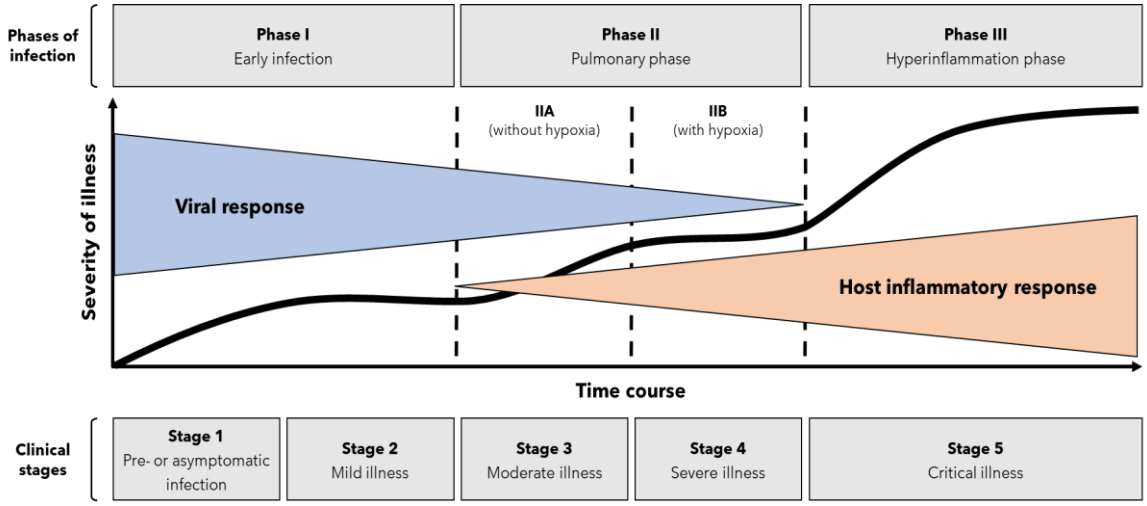

Figure 1 Phases of infection and clinical stages of COVID-19. Adapted from Siddiqi and Mehra (2020), with integrations from Ministero della Salute (2020) and NIH (2021)

clinical stage (presymptomatic or asymptomatic infection) regards the majority of the infected and is characterised by the absence of symptoms. The eventual transition to the second stage (mild illness), which affects far less persons, involves the occurrence of predominantly flu-like symptoms: involvement of the upper airways, fever, dry cough, general malaise, arthromyalgia (joint and muscle pain) and frequent alterations in taste and smell. In (those who are classified as) "healthy" persons, the immune system succeeds in blocking the infection already at this second stage, thus leading to a benign course of the disease.

However, in very few individuals the disease may develop an ingravescent course and evolve into the second (pulmonary) phase. This is characterised by pulmonary changes that lead to interstitial pneumonia with respiratory symptoms (dyspnoea), without (IIA) or with (IIB) hypoxia, detectable by means of a pulse

[4] In fact, all three inferences (inductive, deductive and abductive) allow a growth of knowledge, in varying order and measure, but only abduction is completely dedicated to this aim.

oximeter. Stage IIA (corresponding to the clinical stage of moderate illness) is characterised by a saturation of 94% or higher, whereas in stage IIB (severe illness) saturation is below 94%.

In a limited number of individuals, the clinical picture may further deteriorate and evolve into the third stage of the infection – and thus into the fifth clinical stage of the disease (critical illness). This phase is characterised by a severe respiratory failure caused by (or associated with) elevated markers of inflammation typical of the "cytokine storm". This, in turn, can lead to an Acute Respiratory Distress Syndrome (ARDS), a Multiple Organ Dysfunction Syndrome (MODS) and possibly to death.

In addition to what has already been said, it is worth keeping in mind two aspects regarding the categorization of the phases and clinical stages of the disease. The first is that those are the result of two "distinct but overlapping pathologic subsets; the first triggered by the virus itself and the second by the host response" (Siddiqi and Mehra 2020, 406). The second aspect is that clinical stages do not present themselves as clearly separated in the concrete development of the disease, and therefore several problems may occur simultaneously, especially in the second and third phase.

Given this picture, it is clear that therapies against Covid-19 are very different depending on the goal to be achieved: in one case, slowing down replication and diffusion of the virus in the body; in the other, regulating the reaction of the host immune system. Consequently, it is crucial to administer the appropriate therapy with respect to the corresponding stage, since "pharmacotherapy targeted against the virus holds the greatest promise when applied early in the course of the illness, but its usefulness in advanced stages may be doubtful. Similarly, use of anti-inflammatory therapy applied too early may not be necessary and could even provoke viral replication, such as in the case of corticosteroids" (Siddiqi and Mehra 2020, 406).

As anticipated, the expression "early therapies" precisely makes explicit that such therapies must be administered since the very first manifestation of symptoms, thus before hospitalisation. The distinction between "early" and "home" therapies, therefore, is not simply limited to a terminological level, but has important practical implications: for example, it is possible – as some physicians have actually done – to administer therapies to regulate the response of the immune system (such as those based on cortisone and heparin) even at home; however, in some cases, such treatments were discouraged by the Italian Ministry of Health (see Ministero della Salute 2020, 2021, 2022). Of course, an incorrect "early" therapy – which, for example, uses immunomodulatory drugs at the first manifestation of symptoms – could lead to an aggravation of the disease, and it is precisely to avoid this risk that some physicians, as we shall see, have been wary of early home therapies. In conclusion, beyond the specific drugs used, it is important to understand the rationale behind their administration according to the stages of the disease: on the one hand, to slow or stop the spread of viruses in the body, and on the other hand, to regulate the inflammatory response.

5. A brief history of the debate

After presenting the logic underlying early therapies and the methods of our research, we now pass to the reconstruction of how those treatments were implemented by their proponents and perceived in the Italian public debate. In general, the topic of early therapies was treated almost in a "schizophrenic" way: during the most intense weeks of the first wave, it remained marginal; then, from May 2020 onwards, it assumed a strongly ideological connotation. From December 2020, the discussion on early therapies slowly faded and the topic was addressed only in its (more or less arbitrary) association with the "no vax" galaxy and the legal and

political battles carried out by some of their promoters. Finally, in 2022 Italian authorities accepted the idea of treating the disease in early phases and avoiding hospitalisations as much as possible. This result, still, arrived after a debate that lasted more than two years, in which early therapies and their supporters were often opposed. In the next pages, we will observe in more detail each of the three main phases in which the debate developed.

5.1. Phase one: old frames for a new phenomenon (February-May 2020)

In the first days of 2020, the Italian Ministry of Health had already activated temperature controls on flights from China, while the Council of Ministers declared the state of emergency on January 31st. After the first confirmed cases of Covid-19, the rapid spread of the virus left doctors and health authorities somehow unprepared to deal with the crisis. In fact, although the genetic sequence of SARS-CoV-2 had already been published in January 2020, the virus and the disease were still under scrutiny, thus no specific treatments were available in the first few months. For this reason, several members of the medical and scientific community worldwide were tempted to test for this new virus certain therapies that had proved effective in dealing with other coronaviruses, such as MERS or SARS (Vincent et al. 2005).

As many interviewed practitioners reported, the starting point of the movement of early home therapies in Italy can be set in early February 2020, when a webinar from Pierluigi Viale (head of Infectious Diseases at Policlinico Sant'Orsola in Bologna) took place. In those days, Viale already suggested looking at Covid-19 as a "biphasic" disease, therefore inviting to intervene with early treatments in the first few days of the infection. Drawing on this experience, on February 27th the first network of general practitioners favourable to the implementation of early therapies was formed in Lombardy – the first and most affected region of Italy. Created as a WhatsApp group, "Medici in prima linea" [Doctors on the front line] initially served as a network for sharing information concerning the virus, the disease and the potential treatments. Around mid-March, the team produced a first treatment protocol which called for the treatment of patients from the onset of the first symptoms.

In this same period, several other experiences related to early therapies were born. From March 10th, a team led by Luigi Cavanna (head of oncohaematology at Piacenza hospital) began treating patients at home by administering hydroxychloroquine in the early stages of the disease. In April, the magazine *Time* dedicated to him and his team a report about the project "Heroes of the first lines" (Berardi 2020). Some days later, on March 14th, a lawyer, Erich Grimaldi, created the Facebook group "#esercitobianco" [#whitearmy], in order to connect and offer legal support to doctors and nurses involved in early treatments – a network that will later form the base of the nation-wide "Comitato Cura Domiciliare Covid-19" [Covid-19 Home Therapy Committee]. On March 16th, in southern Piedmont, began "Covi a casa" [Covid at home], a project for early treatment of Covid-19 patients under the coordination of Paola Varese, oncologist and head of the Ovada hospital. Some weeks later, on May 5th, another relevant association promoting early therapies, IppocrateOrg.org, was founded.

Between March and (the first half of) May, the movement of "early" or "home" therapies was saluted with growing attention and appreciation by the Italian press, while the adoption of early/home treatment protocols multiplied in the peninsula also at an official level. The regions of Umbria and Piedmont began early treatments of mild-symptomatic patients with hydroxychloroquine (Imarisio 2020; Pontini 2020), and the Italian drug supervision agency (Agenzia Italiana del Farmaco, henceforth AIFA) approved the off-label prescription of some antivirals (lopinavir/ritonavir) and antimalarials (chloroquine and hydroxychloroquine) in order to treat the SARS-CoV-2 infection (see AIFA 2020a). Meanwhile, important Italian scientific institutions (such as the

Mario Negri Institute for Pharmacological Research and the Veronesi Foundation) expressed some optimism about this kind of treatments (Banfi 2020).

Furthermore, it was during this period that the topic of early treatment was first brought to the attention of politics. In late April 2020, around a hundred thousand doctors (both general practitioners and hospital doctors) sent an open letter to the Health Minister, Roberto Speranza, and to all regional governors, calling for a strengthening of territorial medicine and early treatments of patients with off-label therapies (Quotidiano Sanità 2020). However, the phenomenon of early therapies was about to become the object of a harsh social conflict.

5.2. Phase two: the hydroxychloroquine case and its consequences (May-November 2020)

While the so-called "first wave" of Covid-19 was waning, the debate on home therapies began to be hegemonised by another topic, whose history goes much further than the phenomenon we are interested in for the purpose of this article: the use of chloroquine and hydroxychloroquine. These two molecules have been used since the 1920s to cure malaria, and are now commonly used also in the treatment of lupus and rheumatoid arthritis. Nevertheless, during the first months of the syndemic, these drugs were among the most prominent candidates for the early treatment of Covid-19. Already in March 2020, a team lead by Didier Raoult (director of the Hospitalo-Universitaire Institute in Infectious Diseases in Marseille) had published a largely contested study claiming that "hydroxychloroquine treatment is significantly associated with viral load reduction/disappearance in Covid-19 patients" (Gautret et al. 2020). In the same month, the drug had also attracted the attention of Elon Musk and Donald Trump, giving rise to the peak of its popularity in Google search trends (see Branch et al. 2022).

In Italy, still, the hydroxychloroquine "case" became such just around mid-May, when Donald Trump, former President of the United States, publicly declared he was making use of it. This event suddenly turned hydroxychloroquine into a very political issue, with the drug being associated to populist, sovereigntist, alt-right and anti-establishment stances (Montefiori 2020), in a sort of *political polarisation of science* (O'Connor and Weatherall 2020).

Another turning point in the debate on the molecule was the publication of the result of an analysis on ninety-six thousand hospitalised Covid-19 patients. The study, published on *The Lancet* on May 22nd, claimed not only that the subjects experienced no benefit from the treatment with hydroxychloroquine, but also that they had a significantly higher risk of death due to the insurgence of irregular heart activity (Mehra et al. 2020). Although on June 4th the study was retracted due to issues related to methods and data accessibility, the consequences of these results were huge both inside and outside the scientific community: in the following days, Google apparently suppressed search results for phrases combining the words "Trump" and "hydroxychloroquine" (Sollenberger 2020), the WHO suspended clinical trials on hydroxychloroquine (Mahase 2020) and the Italian AIFA suspended the authorisation to prescribe the drug outside the authorised clinical trials (AIFA 2020b).

Although the scientific debate on hydroxychloroquine continued for some time, eventually the dismissal of hydroxychloroquine as a treatment against Covid-19 got a large consensus. In Italy, moreover, the AIFA (2020c) report on the usage of drugs during this period observed an anomalous increase in the request for drugs

indicated in early therapeutic protocols (especially hydroxychloroquine), thus motivating further caution in the promotion of home therapies as to avoid the risk of incorrect and unsupervised practices of auto-medication.

In the end, the dispute over this drug absorbed much of the debate on early therapies in Italy. After *The Lancet* retracted the study by Mehra et al. and the WHO resumed the clinical trials of hydroxychloroquine in the first days of June (Adnkronos 2020), one hundred and forty general practitioners leaded by Erich Grimaldi filed a legal petition against AIFA, asking to restore the possibility of prescribing hydroxychloroquine, giving rise to a long legal battle that (with alternate successes) continued at least until January 2022. On the media level, instead, the supposed efficacy of the drug began to be framed as a "myth," associated with disinformation and conspiracy theories.

In general, due to the growing polarisation on the topic, the synecdochical absorption of the concept "early therapies" under that of "hydroxychloroquine" and the lack of sufficient proofs on their effectiveness, trust in early therapies slowly but steadily declined. When the first circular of the Ministry of Health on *Home management of patients with SARS-CoV-2 infection* was published, on November 30th, 2020, none of the potential therapies suggested until that moment (antibiotics, hydroxychloroquine, Lopinavir/ritonavir, corticosteroids, heparin) was recommended (Ministero della Salute 2020). On the other hand, another long-awaited weapon against the syndemic was now looming for Western countries: the vaccines.

5.3. Phase three: from vaccines to date (December 2020 – February 2022)

In a rapid succession of announcements about the efficacy of clinical trials and the approval by pharmacovigilance agencies of Pfizer-BioNTech and Moderna vaccines, the last days of 2020 saw the beginning of the vaccination campaign in the United States and Europe. From that moment onwards, the discussion on early therapies will enter in a new and very long phase, largely characterized by a reduction in the number of published articles and a radicalisation of the debate. As the "heyday" of early therapies had passed and less relevant information on the topic became available, we will not describe this third phase of the debate in a strict chronological order, but rather concentrate on some of the main directions in which it developed. In general, we observed three of them.

Firstly, and most importantly, early or home therapies were more and more framed as linked with anti-vax, anti-mask or anti-Covid certificate ("Green pass") positions and movements. Although cases of groups or individual members of associations promoting early therapies who took critical positions towards vaccination or the governmental countermeasures to the syndemic are documented, the phenomenon was largely oversimplified, as the "front" of early therapies was far from being unitary and internally homogenous. While many articles drew on this simplistic association and contributed to crystallise such a view, others pointed to considerations of a different kind. Some argued, for example, that early therapies were *not* (to be considered) alternatives to vaccines, or that the association between early therapies and opposition to vaccines was *unduly* exploited by the proponents of the latter.

An element that probably contributed to the above-mentioned simplification could be traced back to the second dominant theme of this phase: the irruption of the issue of early therapies into the sphere of politics. Since the second half of 2020, the reluctance of political and health institutions to integrate practices and protocols of early treatment into the official guidelines steadily grew, as the discontent on the part of the promoters of early therapies. Together with the ongoing legal battles related to the authorization of off-label prescriptions, all these elements fuelled a climate of increasing polarisation of the issue, which eventually

resulted in properly political phenomena. First, a component of the "front" supporting early therapies actually moved its claims on the political terrain, when in April 2021 Erich Grimaldi founded the "Unione per le Cure, i Diritti e le Libertà" [Union for Cures, Rights and Freedoms], a sort of political platform in support of the "Covid-19 Home Therapy Committee". In the second place, some political figures began to endorse the promotion of early therapies and their integration into national protocols[5].

A third tendency, finally, revolved around the discussion of new scientific results, leading to a kind of re-legitimization of early therapies. April 2021 saw the publication of a protocol developed by (among others) Fredy Suter and Giuseppe Remuzzi, emeritus head physician of the Papa Giovanni XIII Hospital of Bergamo and director of the Mario Negri Institute of Pharmacological Research respectively. This study argued for the efficacy of nonsteroidal anti-inflammatory drugs in combating the infection of SARS-CoV-2 and reducing hospitalisation, provided that they are administered at the onset of the first mild symptoms of the disease (Suter et al. 2021). Later on, in winter 2021-2022, AIFA authorised the use of monoclonal antibodies, and the prescription of three antivirals (remdesivir, nirmatrelvir/ritonavir, molnupiravir) based on their ability to stop the replication of SARS-CoV-2 if administered within the first five/seven days after the onset of symptoms (AIFA 2022). All these indications, commonly pointing to the necessity of intervening at an earlier stage of the disease, were then integrated in the third and (currently) last version of the ministerial guidelines on the *Home management of patients with Sars-CoV-2 infection*, released on February 10th, 2022 (Ministero della Salute 2022). In conclusion, the core logic underlying the treatment of Covid-19 patients with "home" or "early" therapies was eventually recognized by both political and health authorities as a useful weapon to contrast the disease caused by SARS-CoV-2. Nonetheless, some of the strategies implemented by their promoters, the reputation of doctors, general practitioners and groups advocating early therapies and the very label of "early" or "home" therapies underwent a very controversial, and at times harsh, treatment. One last question arises: why so?

6. The causes of a (relative) failure: complexifying the picture

For some years now it has been possible to observe in the public debate – both in Italy and abroad – a tendency to flatten the complexity of phenomena characterised by a multiplicity of heterogeneous but mutually interacting factors on the epistemic dimension alone. As we observed before, this kind of polarisation appears to have affected also the debate on home therapies in Italy. At least in the media coverage of the phenomenon, the bad reputation of those treatments derives primarily from two *primarily epistemic* considerations: 1) scientific studies have shown that early therapies are not effective, and those claiming the contrary claim something false; 2) therefore, those who accept or advocate early treatment act on ideological rather than rational or scientific grounds. Of course, this is not to say that such considerations are completely wrong. On the one hand, some scientific studies have demonstrated the inefficacy of some drugs used in early therapies; still, assessing the efficacy of those treatments in general is a very complex aim. On the other hand, it is true that some individuals have indeed exploited home therapies to their advantage for ideological reasons, but the same does not apply to all their promoters.

[5] A systematic overview of the positions adopted by different leaders, movements and political parties about early home therapies is beyond the scope of our article. Among the most relevant cases at national level are two initiatives held at the Italian Senate in November 2020 and September 2021 (promoted by representatives of the *Five Star Movement* and the *Lega*, respectively). The leader of the party *Brothers of Italy* also informally endorsed early home therapies in different occasions.

What we want to argue is that looking at the issue of early therapies from the sole epistemic perspective can be extremely reductive and incapable of accounting for the complexity of the phenomenon. On the contrary, looking at early scientific care protocols as socio-technical objects (Lakoff, 2008) makes it possible to consider their predisposition and acceptance as influenced by the congeries of cultural, political, scientific, economic and biological dimensions we identified. By observing them both in their specificity and in their interaction, we will provide a more complex, and nuanced, picture of the factors that have favoured or disfavoured the development of home care protocols.

6.1. Medical-scientific expertise

One of the central dimensions for the development and implementation of protocols is, of course, that of medical-scientific research. This is, in fact, the proper field in which different therapeutic options are discussed, theorised and scrutinised; and it is from this discussion that treatments obtain their first "licence" of efficacy or inefficacy. As it is obvious, though, these processes do not take place in the abstract world of theory, but within complex social systems that concern the training and specialisation of doctors and researchers, their insertion into specific health systems, the economic and cultural constraints that inevitably direct the lines of research and investment, etc. Therefore, all these elements must be considered in order to analyse more thoroughly the medical-scientific side of the phenomenon of home therapies.

6.1.1. Observing "different" diseases

Obviously, the predisposition of any protocol is closely linked to the nature and developments of the disease it aims at treating. In the case of Covid-19, though, there was no immediate consensus on the pathogenetic phases and stages it is characterized by, which deeply influenced the reputation of early therapies.

Especially in the first months of the disease spread, the treatment of patients in two different settings (hospital and home) led hospital and territorial doctors to observe the disease from different points of view, as they focused on different clinical stages: critical or severe in the first case; mild or moderate in the other. According to an interviewee, it was as if doctors, depending on their point of view, were actually dealing with "different diseases" (Interviewee n.5)[6]. It is therefore understandable that different therapeutic options were being tried out in the hospital and on the territory; as it is to assume that this discordance fuelled a certain distrust towards early therapies. Since hospital doctors had to focus on already aggravated clinical pictures, they might have had some difficulty in understanding the rationale of early therapies. Also because some drugs with antiviral function (which were potentially effective in the early stages of the disease), appeared to be ineffective in the hospital setting, as they were administered too late, in more advanced clinical stages.

[6] Attributes: central Italy, general practitioner, no scientific research, very favourable towards vaccines, no affiliation to early therapies movements.

6.1.2. Medical specialisation

Even the different specialisations within medicine have contributed to diverging opinions about early therapies. Certain medical figures that do not directly visit patients, thus making no experience of a contact with the virus (such as infectivologists, immunologists, microbiologists or virologists), could have been more unconfident towards those treatments. Obviously, it was not always the case – as our interviewees, that come from different fields of medical science, show –, but in general the differences in medical expertise may have introduced a certain incommunicability and incommensurability of perspectives (Kuhn 1962).

As far as hospital doctors are concerned, an interesting category was that of oncologists, some of whom actively promoted the use of early therapies: two of the best known and most influential Italian figures in this regard were in fact oncologists. Despite the different approaches followed, they shared the rationale for early intervention and the consequent approach to the disease, which derives from the very approach of oncologists: on the one hand, in fact, they are particularly careful to avoid as far as possible the hospitalisation of patients with a compromised immune system; on the other hand, they often resort to therapies (such as immunotherapy of tumours) that focus on the action of the immune system, in a similar way to the immunomodulating therapies used to treat Covid-19. As an interviewee put it:

> When I have to manage infections and we talk about a patient who does chemotherapy […], until he gets a fever I keep him at home because he is more likely to get sick in the hospital. [...] this is a cultural background that any doctor who deals with the immune system […] has (Interviewee n.6)[7].

6.1.3. General practitioners' training

Another aspect contributing to the resistance towards home treatments concerns the unsatisfactory training of general practitioners. Especially during the "first wave," they clearly found themselves in a particularly difficult situation: they represented the first barrier against the spread of a very little-known disease they had to face without a solid supporting structure. Yet, in most of the interviews conducted, the unpreparedness and poor training of general practitioners were cited both as a determining factor in preventing the understanding of home care protocols and as reasons explaining the distrust of institutions towards this category of doctors. Moreover, it is worth remembering that the associations promoting home therapies were born precisely out of training events (e.g. the webinars by Pierluigi Viale) and the need to share information and experiences gathered at that point. This necessity was particularly felt within the associations and the hospital doctors who decided to focus on early therapies: in both cases, self-training groups were organised, as well as mentoring systems in which doctors with more experience in the treatment of the disease followed those who had treated few Covid-19 patients yet.

6.1.4. Methods for validating therapies

[7] Attributes: northern Italy, health care manager, full-time scientific research, favourable towards vaccines, affiliation to early therapies movements.

A further factor that hindered the publicity and dissemination of early therapies concerned the diversity of and incommunicability between the different methods for validating a therapy.

As it is known, in the field of medical research there is a hierarchy of sources that assigns different degrees of evidentiary force to different research designs. In this sense, the so-called "gold standard" (Hariton and Locascio 2018) is represented by *randomised controlled trials*: prospective studies – i.e. those whose entire research design must be planned prior to the administration of the treatment – in which participants are assigned to experimental and control groups according to a randomised procedure. According to a hierarchy that, although widely accepted, is not without criticism (Vandenbroucke 2008), in a subordinate position follow the so-called retrospective studies, i.e. those characterised by the collection of data on the efficacy of a treatment only after it has been completed.

In the context of home therapies – and especially in the first phase of the syndemic – no one could guarantee the level of organisation necessary to carry out randomised controlled trials, which involve sophisticated sampling mechanisms and the use of a considerable amount of resources. Therefore, research on home therapies could only rely on retrospective studies. Yet, to conduct systematic research in a domiciliary, and thus non-hospital, setting involved considerable organisational difficulties: doctors working on the territory could not rely on specialised centres (such as hospitals and research institutes) and were forced to deal with the bureaucratic and data collection procedures by counting on their own forces. As an interviewee put it:

> Developing a research protocol on the territory is very difficult, because you don't have resources, […] you don't have people dedicated to that […]. There are various levels that even an hospital in its own small way can manage, because it is a centralised structure with all the necessary information, and all the steps can be done there (Interviewee n.5).

On these bases, it is not surprising that the Italian studies on the efficacy of early home therapies were few in number and retrospective in nature. In fact, they were published only by the few research teams that could count on the support of specialised structure. Consequently, "the majority of studies on Covid-19 patients [both retrospective and prospective] concern hospitalised cases" (Cavanna et al. 2021, 66) and "data on early outpatient treatment are limited" (*ibid.*, 61).

These factors, as a whole, led to a structural difficulty in assessing the efficacy of early therapies. On the one hand, the (retrospective) studies responding to the rationale of early home therapies received little attention by the scientific community, as they were considered to have less evidentiary power; on the other hand, some prospective studies testing the efficacy of certain drugs used in home therapies were conducted on patients who had already been hospitalised, and thus did not generate useful data to assess the efficacy of treatments in the early stages of the disease.

6.1.5. Financial investments in scientific research

In the background of the processes regulating medical-scientific research, one cannot ignore that the evaluations of expense and profit of the actors involved play a major role. As to the private sector, our interviewees pointed to the "co-interest of pharmaceutical companies, and [to] a very serious responsibility [...] of universities" (Interviewee n.6). Driven by the legitimate goal of maximizing their profits, pharmaceutical companies directly intervened in funding studies that involved drugs with higher costs – while,

on the other side, universities and research centres had all the interest in obtaining funding. According to an interviewee who is highly favourable toward vaccines, the same process also applied to the research on the latter. In the case of vaccines, moreover, pharmaceutical companies could even benefit from substantial public investments.

> These therapies were hindered […] substantially and first and primarily for an economic reason. […] as I pointed out, monoclonals, paxlovid and monupiravir cost hundreds of euros compared to the few euros of hydroxychloroquine and ivermectin. On the other hand, because early therapies and vaccination were framed as in competition (Interviewee n.14)[8].

In this way, though, research on cheaper treatments that promised some efficacy was overshadowed, and the very possibility of conducting more comprehensive studies on their actual potential was hindered.

> Unfortunately, there was only room for a line of research to study vaccines and antivirals, and the pharmaceutical market fuelled it […]. [For studying home therapies] there was no interest nationally or globally, I think, […] but I'm not talking conspiracies, I'm talking that seriously: if you want to [invest in early therapies] you have to put funds on stuff like that. [Otherwise] if something works but you don't have proof of it, it will never become a scientific evidence (Interviewee n.5).

As the last interviewee suggested, public institutions themselves were not interested in investing in the research on early home therapies, for at least two reasons. On the one hand, the public sector alone would have to bear the entire costs for these studies, since pharmaceutical companies simply had no interest in co-financing them; on the other hand, public institutions considered more useful to direct investments in the production of vaccines – also on the basis, as we will later see, of political decisions.

Finally, such economic considerations had an important impact on the unequal allocation of drugs at a global level. Several interviewees highlighted that the Western world will have access to the best and more expensive drugs, while countries with fewer resources will be forced to rely on less safe or effective therapeutic options.

6.1.6. Cultural prejudices within medical science

A last element emerging from the interviews is a sort of ethnocentric bias against the Chinese and, more generally, non-Western scientific world. Much of the knowledge that has now become established – and forms the basis of the rationale for home treatment – was already available in the early 2020s, yet it was somehow ignored. In January 2020, *The Lancet* had published some studies by Chinese researchers that analysed both the pathophysiology of Covid-19 and the possible therapies to prevent the disease exacerbation. Yet, due to their national origin, these results were only marginally considered by the Western medical-scientific community, thus generating a certain delay in both the evaluation and development of these lines of research.

[8] Attributes: northern Italy, hospitalist, full-time scientific research, favourable towards vaccines, no affiliation to early therapies movements.

Two different (but interrelated) explanations for this distrust emerged from the words of interviewees: on the one hand, they referred to the suspects about Chinese scientific standards, which are considered not always adequate or bent to the needs of the national political system; on the other hand, they mentioned a certain indifference and suspect towards the scientific production of non-Western countries. A proof of the relevance of the issue comes from the words of Remuzzi. In an interview to *Corriere della Sera* (February 21st, 2022) he reported that when he read the Chinese articles his reaction was

> the one that everyone had: who knows if it's true, and in any case [the virus] will never reach us. We didn't believe it. Although medically advanced, China is still a long way off […]. The scientific community, which I am part of, bears a huge responsibility for the disaster of the past two years (Imarisio 2022).

6.2. Media and the public sphere

Needless to say, the public representation of early therapies played a major role in influencing their reputation. Far from merely mirroring what happened in the political and the medical-scientific debate, the media actively contributed to the construct of the social phenomenon labelled "home therapies" and fuelled its discussion within the public sphere. The intricacy of the topic, nonetheless, has obviously made it difficult to provide a complex and complete view of the phenomenon, especially with regard to the popularization of the positions and the scientific debate on early therapies and the relation between therapies and vaccines.

6.2.1. Simplification of positions and scientific debate

Since they are aimed at non-specialized audiences, media have an innate tendency towards simplifying the results of scientific research. As for the studies on early therapies, however favourable or unfavourable, they were somehow deprived of their complexity in the public discussion. Every time a research was published, the treatments it dealt with were presented as simply inefficient or efficient, although data might have been still provisional and in need of further investigation. Even the specifications provided by the authors of the studies or their retraction struggled to change such sedimented images, if they had achieved enough success in the news and rooted deep enough in public opinion.

> We are in media's hands. If what you write punches through the vulgate of scientific journalism, you are no longer in control [of it]; rather, if you say "actually, take my study with a grain of salt," they will immediately look for someone who maybe has not done the study you have but tells that it works (Interviewee n.12)[9].

Moreover, as several interviewees reported, doctors and scholars with the greatest media presence during the syndemic were often highly critical of early therapies; whereas, in contrast, those who looked favourably to these treatments rarely appeared on major national networks and news outlets – and even when it happened, they were subjected to harsh attacks and criticism. This, in turn, dragged home therapies into a sort of

[9] Attributes: central Italy, hospitalist, full-time scientific research, favourable towards vaccines, no affiliation to early therapies movements.

informational vicious circle: the few promoters who kept talking about them did so in less distinguished and respected programs or news outlets, while many others (especially those who occupied important positions in health institutions) simply stopped exposing themselves publicly on the subject, fearing the reputational damage they could suffer in a debate that was becoming increasingly heated.

The polarisation of positions on early therapies, finally, was partly alimented by the increasing politicisation of the issue. As anticipated, the "hydroxychloroquine case" fuelled a literal social conflict between some movements interested in guaranteeing the prescription of the drug and the health institutions that opposed it. The legal disputes arising thereof required repeated interventions by the regional administrative courts, and in the long run led to an actual mobilization of (some of the) proponents of early treatment: in April 2021, the "Union for Cures, Rights and Freedoms" took to the streets to protest the government's indifference to engage in a discussion to draft a national protocol for early treatment. In the public sphere, these demonstrations were often associated with exponents of "no-vax," "no-mask" and "no-Green pass" movements, as well as with the sovereigntist component of the Italian political spectrum. This interpretation of the conflict on early therapies, however, was not completely justified: on the one hand, the politicized fringes of the movement (that in some cases were actually critical of vaccines, mandatory masks and vaccination certificates) were representative only of its most "extreme" component; on the other hand, many doctors who used hydroxychloroquine (or other drugs whose use was restricted) eventually adapted to the indications of pharmacovigilance and explored other therapeutic options without engaging in further conflict.

6.2.2. Relation with vaccines

Most probably, the central factor which contributed to the simplification, polarisation and politicisation of the debate on early therapies was the discussion about their relations with vaccines. We have already seen that when the prospect of obtaining vaccines against Covid-19 became more realistic, early therapies were increasingly framed as an alternative to vaccination. Apart from the media, who certainly played an important role in crystallizing this association (often but not always improper), our interviewees also ascribed the responsibility of this to the scientific community and political institutions themselves.

Among the various reasons that led those institutions to discredit early therapies, one was certainly the fear that those treatments could be instrumentalised by vaccine critics or opponents. As a matter of fact, in some cases this possibility materialised: several members of associations and movements promoting early therapies actually took critical stances toward vaccines or refused to vaccinate at all – and were therefore subjected to disciplinary proceedings or banned from the medical profession. Yet, these episodes represented only a small part of the vast and complex movement we are interested in. As the very rationale of those early treatments does not necessarily lead to consider them as alternatives to vaccination, almost all our interviewees portrayed this image as a major distortion of the phenomenon. On the contrary, they explicitly referred to early therapies as an instrument to be supportive of and combined with vaccines (interestingly, regardless of their personal views on the latter): "vaccines and therapies are complementary" (Interviewee n.7)[10].

Some interviewees (even those in favour of vaccination) did not conceal their belief that the association of home therapies with no-vax positions was due, at least to some extent, to deliberate information campaigns: now for political, now for economic interests. Finally, it emerged from several interviews that this coverage of

[10] Attributes: southern Italy, general practitioner, no scientific research, unfavourable towards vaccines, no affiliation to early therapies movements.

early therapies prevented any possibility of legitimising them within the scientific community, thus opening up the space for the proliferation of alternative therapies without scientific basis.

6.3. Institutional regulation

When asked to comment on the role that health and political institutions played in the rejection of early home therapies, all interviewees pointed to their direct responsibility in one way or another: overall, the very way institutions responded to the spread of the disease explicitly discouraged the development of early home treatment protocols. As for the reasons, at least four can be identified.

6.3.1. From optimism to caution

When the SARS-CoV-2 infection had not reached Europe yet, there seemed to be some confidence in the ability of the national health systems to respond adequately to the eventual spread of the disease, as was the case with other epidemics (e.g. Avian flu and SARS). At that stage, European institutions imagined that finding adequate cures and/or containing the spread of the virus would be a relatively easy task. However, when it became clear that Covid-19 was putting a strain on the Italian health care system, a radical shift in attitude occurred: from a very "optimistic attitude," institutions turned to a "cautionary attitude" (Interviewee n.12). In the management of the syndemic, this change had the dual effect of moving treatments against Covid-19 patient to the hospital setting and limiting the role of general practitioners to monitoring of the patient and administrating, at most, a symptomatic therapy (i.e. intended not to cure a pathological state, but only to treat or remove its symptoms). This choice was motivated by the fear that general practitioners may misuse drugs with antiviral function, and especially anti-inflammatory and anticoagulant drugs. In the first wave, a period when hospitals in the northern and central regions of the country were overburdened, this attitude generated a real short-circuit: "Firstly, there was a problem of diagnosis, because in March-April, it was impossible to perform [Covid-19] tests. […] Also, it was very complicated to get patients to the hospital, there were no preferential routes" (Interviewee n.5).

This cautionary attitude of the institutions is nothing but the political side of the dynamics of the scientific community we already mentioned. As in the emergency it was impossible to rely on evidence-based medicine, it was necessary to follow a clinical approach based on the direct experience of doctors and the knowledge of the pathophysiology of Covid-19 (and, by analogy, of other similar diseases). Nonetheless, the institutions decided not to give any specific guidance about those treatments, precisely because of their "defensive" attitude:

> [in general, you should] act only where there is proven evidence through clinical studies. But when there is no time […] what can you do? Do you wait for clinical studies and then, two years later, you say "Yes, it worked, then we can use this tool"? This, however, created a conflict: on the one hand, some were pushing to do something based on a rational [i.e. empirical] approach, clinicians of high level too […], while others remained completely tetragonal to any kind of suggestion, including our ministry. The board of experts entrenched behind this vision of safety, because in the end [if you didn't say anything] you weren't saying anything wrong […] After a while, this idea of defensive medicine prevailed at all levels, even at the political one (Interviewee n.12).

6.3.2. The focus on vaccines

If the absence of scientific studies based on randomized controlled trials had been the only reason for institutional resistance, a greater openness toward early home therapies should have been expected over time. Yet, this attitude of distrust paradoxically reinforced: subsequent regulatory interventions further reaffirmed both the centrality of the hospital and the limitation of the functions of territorial medicine. Indeed, in November 2020 the ministerial circular explicitly formalized this prudential attitude through the publication of a protocol based on paracetamol and "watchful waiting". To explain this further resistance of the institutions, some interviewees referred to the governmental strategy of focusing mainly on vaccinations to cope with subsequent infection waves. It should be noted that this tendency, (to favour vaccines rather than focusing on both the vaccine and early home therapies) was emphasized even by those respondents who have a very favourable position with respect to vaccination and its compulsoriness:

> When the policy maker understood and knew for sure that effective vaccines would soon be coming, he made a right choice of field, that is "let's bet everything on vaccines" […]. And it made the choice to overshadow everything that could appear as an alternative to vaccination, including home therapies, because it perfectly knew that there was a very strong no-vax movement all over Europe that would immediately and pre-emptively take up arms (Interviewee n.12).

Although some medical experience had been accumulated during the first wave and the pathophysiology of SARS-CoV-2 infection was then clear, the persistent underestimation of early treatments did not allow to change the way Covid-19 patients were managed. As in the first wave, almost all therapeutic interventions were confined to hospitals, which consequently had many difficulties in managing patients:

> On the one hand, we knew that hospitals did not have sufficient capacity and ability to handle [them] […]. In the second wave, however, [it seemed as if we had] learned nothing from the first (Interviewee n.5).

6.3.3. Internal economics of the health system

The tendency to centralize the management of Covid-19 cases to hospitals at the expense of territorial structures was also attributed to some economic reasons regarding the financial management of the health system. In an interview, for example, this process was connected to a twofold trend that characterises the administration of the Italian public health system: a long-standing decline in investments in public health, resulting in the expansion of the private sector; and a disempowerment of territorial healthcare in favour of large hospital facilities. Both strategies, nonetheless, revealed to be inefficient in the wake of the emergency:

> The other bullshit [*sic*] that Italy has done in the past two decades is decreasing public funding in health care in favour of privates […] Public hospitals found themselves on their knees in running emergency rooms (Interviewee n.10)[11].

[11] Attributes: northern Italy, hospitalist, full-time scientific research, very favourable towards vaccines, no affiliation to early therapies movements.

A second element, instead, regards the economic interests of hospital themselves. In a situation of declining and insufficient public expenditure, hospitals are more and more interested in securing as much funding as possible from the state, so they can plan internal investments. According to some interviewees, though, this strategy deeply impacted on the management of the syndemic. Since hospitals are granted different amount of money based on the different types of patients admitted, it was in their best interest to admit Covid-19 patients, for whom government funding was higher: "In a hospital, a Covid-19 patient costs much more than a normal one […] and so there was an advantage for hospitals in having [Covid-19] patients" (Interviewee n.9)[12].

This concern of hospitals to receive as more funding as possible, moreover, caused further disinterest in the development of territorial medicine (and consequently of a system of early home therapies) and led to overcrowding the hospitals themselves (thus making it difficult to appropriately take care of all Covid-19 patients).

6.3.4. The role of territorial medicine

In order to avoid the overloading of emergency rooms, territorial medicine was reserved only the role of a "filter" before the hospital. Nonetheless, it was essentially relieved of any therapeutic function. Hospital doctors who decided to focus on home therapies, in fact, had to organize home support services themselves. Our survey showed that basically two different models were followed: in the first case, it is "the hospital leaving the safe and secure walls and going to the territory" (Interviewee n.6), i.e. using hospital staff and equipment to organise a home support service. In the second model, hospital doctors worked closely with general practitioners and with the Care Support Units specifically created to assist Covid-19 patients nation-wide (USCA – *Unità Speciali di Continuità Assistenziale*) through informal networks of information and coordination.

> We supported general practitioners with all the means we had. It is mostly thanks to these chats, but not only ours [...] which, in fact, continue even more intensively, even with more adhesions because they are also psychotherapy chats, because when one did not know things, there was someone else who had the answer and we saved time (Interviewee n.6).

The lack of precise therapeutic indications in the prehospital phase generated an enormous inhomogeneity of treatment and posed a difficult obstacle to overcome for those who tried to build independently some coordination between hospitals and the territory. This generalised lack of organization, added to the structural lack of investments, has been interpreted by some as one of the main causes of Italy's high mortality rate:

> How come no one wonders why so many more deaths in Italy than in Germany, for example? Or in France or Spain? Why? The people are the same, the virus the same, but the number of deaths that we had is not even remotely comparable to the number of deaths that our neighbours had, right? So how do you

[12] Attributes: central Italy, general practitioner, no scientific research, very unfavourable towards vaccines, affiliation to early therapies movements.

> explain that? There is one variable that makes the difference: [our] local and national disorganization (Interviewee n.10).

6.4. Agency of patients, viruses and drugs

If we were to limit our analysis to the above-mentioned elements, we would see the history of early home therapy protocols as being tied exclusively to the dynamics of the medical-scientific, institutional and mediatic world, thus obtaining a simplistic picture of its development. Indeed, a well-established literature has shown that it is necessary to take into account the role of other two subjects: on the one hand, patients and citizens, who play an active role in the way therapies are implemented and in their evolution (Epstein 1995); on the other, according to Actor-network theory and the principle of symmetry (Law 1992), non-human actors, such as drugs and the virus itself.

6.4.1. Patients and citizens

Patients have actively intervened in the dissemination and design of early treatment protocols in multiple ways. First, it is the very health condition prior to SARS-CoV-2 infection that positively or negatively affects the progress of a therapy. As we have seen in the previous sections, it was precisely the fear that general practitioners did not know how to adequately tailor home therapies to the specific conditions of patients that partly fuelled some hospital doctors' distrust towards protocols. In addition, precisely because the administration of therapy takes place in a home setting, patients have wide margins of discretion with respect to the ways and times of taking medications: not by chance, many doctors engaged in home therapies complained about a certain difficulty in monitoring patients continuously – an element which in some cases has led to an incorrect application of the protocol.

Finally, a substantial part of the uptake of home therapies depends on how their success or failure is perceived by patients themselves. In this regard, it is worth pointing out that the main associations of home therapy doctors in Italy observed a steady growth in requests for intervention (especially from people who were not regular patients of these doctors). Moreover, the (potential) recipients of home therapies actively manifested their support also outside therapeutic settings: important public initiatives regarding home therapies – among all, the demonstrations organized by the Union for Cures, Rights and Freedoms – saw the mobilisation of thousands of patients and ordinary citizens.

6.4.2. Viruses and drugs

Last but not least, it is important to keep in mind the agency of both viruses and drugs in the development of a protocol. Whether viruses are inanimate beings or particularly simple forms of life is a matter of debate; what is certain, and most interesting, is that viruses evolve and mutate when they come into relationship with the cells of the living beings they reproduce within. Hence, the evolution of a virus to a form that is more or less aggressive to the host is not an aprioristic result of the genetic makeup of the virus, but depends on many variables, including its spread in the population and the way that population acts. Therefore, there is a circular relationship between therapies against Covid-19 and the virus' mutations: an aggressive mutation tends to make home therapies less effective, and therapies in turn retroact on the way the virus mutates. Conversely,

"[as] the Delta variant was already more contagious but less virulent than the initial variant, it is clear that if you organize a home therapy group [at that stage] you get better results" (Interviewee n.12).

As for the agency of drugs, it is certainly related to the efficacy of the active ingredient with respect to the desired outcome. However, as we repeatedly suggested, it also concerns other variables that are often neglected, but nonetheless deeply affect the preparation and dissemination of protocols: such as the simplicity in administration and/or conservation, the costs of production and distribution or the regulations concerning prescription.

7. Conclusions

As we argued in the previous sections, the approach of politicisation of science seems unable to properly understand the issue of early home therapies. Although the topic was addressed also in the political agon and generated a great deal of polarisation, it would be reductive to explain the issue solely on the basis of cognitive and cultural biases, distrust toward science or disinformation. In fact, in the case of a long and complex process such as protocol adoption, it is not easy to put a clear and conclusive boundary between the spheres of science and politics, since the two are blurred and continuously interacting. Moreover, the normative view of science which implicitly inspires the approach of politicisation of science fails to account for some constitutive, albeit less visible, aspects of the scientific enterprise that we emphasised: the difficulty of obtaining adequate scientific evidence in emergency situations, the variety of scientific evidences that can be relied upon, the structural limitations of the systems within which physicians and scientists operate, the sometimes diverging logics that move healthcare organizations, and the different levels at which health care intervention is articulated.

Rather, considering medical protocols as socio-technical objects allowed us to highlight the large and multifaceted set of medical, scientific, economic, cultural, political (and even biological) process that influence their development, evaluation, and implementation. As to the phenomenon at hand, we observed that several aspects pertaining to different but interconnected spheres contributed to difficulties in producing and promoting protocols of early home therapies in the Italian case. In this regard, to describe those protocols as a mere failure may be not only ungenerous, but even imprecise. Not least because by our reconstruction emerge an underlying contradiction and three unresolved problems, which we would now like to point out.

The contradiction we identified consists in the fact that, although promoters of early therapies were often opposed and marginalised, their essential message was eventually accepted. Far from being restricted to the administration of some specific drug, the logic of early home therapies consisted in the need to start treatment as early as possible, especially in subjects at risk, and in regulating the inflammatory response once the patient enters the more severe stages of the disease; with the ultimate goal of reducing hospitalisations as much as possible. It is precisely this "legacy" what survived the debates over specific drugs and got to be recognized by top scientists (Perico, Cortinovis, Suter and Remuzzi 2022), institutions and media. Proof of that, the last version of the ministerial protocol for home treatment of Covid-19 patients and the last guidelines published by AIFA actually recommend the administration of antiviral treatments in the first days after the onset of symptoms, as the use of immune-modulating therapies in later stages. Nonetheless, the whole issue of early home therapies quickly went under the radar, only to re-emerge two and a half years after the onset of the syndemic, albeit without the media and political hype of the first phases of the debate. Now that the issue seems to have lost its divisive character, early home therapies are considered an important strategy to govern

the syndemic, to the extent that they can be considered capable of reducing the pressure on hospitals by 85-90% (Cuppini 2022). Yet, not surprisingly, the very treatments recommended by AIFA are still under-prescribed (Bartoloni and Gagliardi 2022).

Despite this partial success of the logic of early therapies, though, some problems in this regard remain unresolved. First, we are still faced with a lack of clarity about the administration of some of the drugs promoted by the protocols of early home therapies – namely, those in which no major economic interests are involved. Because of the organizational difficulties we have repeatedly pointed out, studies in this direction are scarce, or yet unpublished – and in the absence of substantial investment by public and independent institutions it could not be otherwise. Here, then, the second problem arises: because of their "cautionary attitude," health and political institutions appeared (and partly still appear) unwilling both to take a clear position on the adoption of early care protocols, and to take charge of the responsibility to fund independent research on the topic. This strategy, moreover, impacted on a third level: that of the disorganisation and underfunding of healthcare facilities necessary for an extensive patient monitoring and the construction of a system of home care that may prove effective on the territory.

What the debate on home care in Italy clearly shows, in the end, is the need to strengthen territorial medicine and rethink its relationship with the other levels of the health system – necessities that cannot but be implemented through proper *political* decisions aimed at increasing investments in this regard. Since the announcement of their activation, the Next Generation EU funds have been regarded as a major opportunity for Italy to take the first steps toward this direction. Yet, the recent downsizing of the Care Support Units, "the more precious legacy of the whole pandemic" (Interviewee n. 6), seems to point exactly to the opposite one.

Although the results of this research emerge from, and apply to, the specific Italian case, a wider and more comprehensive assessment of the issue of early home therapies may benefit from a comparative analysis. We have previously outlined the difficulties encountered in this type of investigation; however a further research path could be explored along the different domains we identified: how is the public debate structured in other countries, and how was the issue of early home therapies addressed? What are the continuities and differences in the organization of healthcare systems compared to Italy, and what role (if any) did they play in the formulation and acceptance of protocols of early treatment? How is scientific research organized in those contexts, and what role do public institutions play in its regulation. However different the answers may be, one thing we consider certain: a systematic analysis of similar questions must be based on a complex and multifocal perspective, capable of identifying and connecting the several factors that contribute to the development of socio-technical-scientific objects (and their public discussion). We hope that, at least on this need, our contribution has helped to shed some light.

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