Research Ethics and Ethics of Treatment for Covid-19

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Caporale started off by pointing out the two stage phase for the ethical approval of clinical trials in Covid-19 times in Italy. The first step is AIFA (the Italian Agency for Pharmaceuticals) that, through the CTS (Technical Scientific Committee) approves it or not. Notably, they do not look into **informed consent**. Second, the ethical committee kicks in (if AIFA does not approve the trials, it does not even consider them). As there is the need for an agreement between both institutional bodies, this procedure limits the disagreement. Thanks to an improvement in the collaboration between different parties (i.e. researchers, ethicists, doctors, scientists, etc.) the **time frame** for results from months to hours at times.

A number of problems have come to light during the pandemic.

To begin with, there is a large **variety** of modules between studies. They can be different between **observational** and **experimental** type of studies, they change if they are **independent** or **sponsored** trials and it is very important where they are carried out (North/South of the country, hospital, IRCSS, and so on). Some modules are extremely explanatory (but possibly too long) while others might be very approximate or short (in particular, those patients from remote are given minimal length modules).

The second problem one faces with **Covid-19** is the absence of a **standard therapy** to refer to. This has created the conditions for a particular attention from doctors and researcher to care for patients beyond their autonomy as their informed consent could be questioned in its essence: what exactly are they consenting to as we are not able to provide them with certain data to begin with? As informed consent has been substituted by the opinion of **ethical committees** during these times, one has also to wonder if we have paved the ground for a full-scale re-dimension of **individual autonomy**.

Lastly, the **acquisition** of informed consent is another, deeply problematic, issue that needs attention. During the pandemic, it has been really difficult to physically collect informed consent with **standard procedures**. For example, posthumous consent from dead patients (whose medical data would have been particularly relevant and timely for helping research on Covid-19) was not possible.

Other practical problems concerned the informed consent form itself (as papers and pens could have function as spreaders for the virus, they were not allowed in the hospital facilities anymore) or even the registration (**e-consent**) had problems as for the same reason, digital recorders and other tools were not allowed either. This situation led to get informed consent in an internal dynamic in which nurses functioned as **witness** for doctors to collect it -raising more than an ethical doubt over the appropriateness of the procedure.

A conclusive sidenote is the **paradox** of participating in a trial related to covid-19. While **outside** of the study all patients received the **experimental medicine** (i.e. Remdesivir) because no one really knew what was going to happen next, when participating, patients know that they had a 50% chance not to get any treatment -making the participation not very tempting.